Research 1: Depth and thoroughness of research

Subject: An investigation and redesign of the Speculum instrument to understand clinician needs and to also reduce stress and discomfort for patients.

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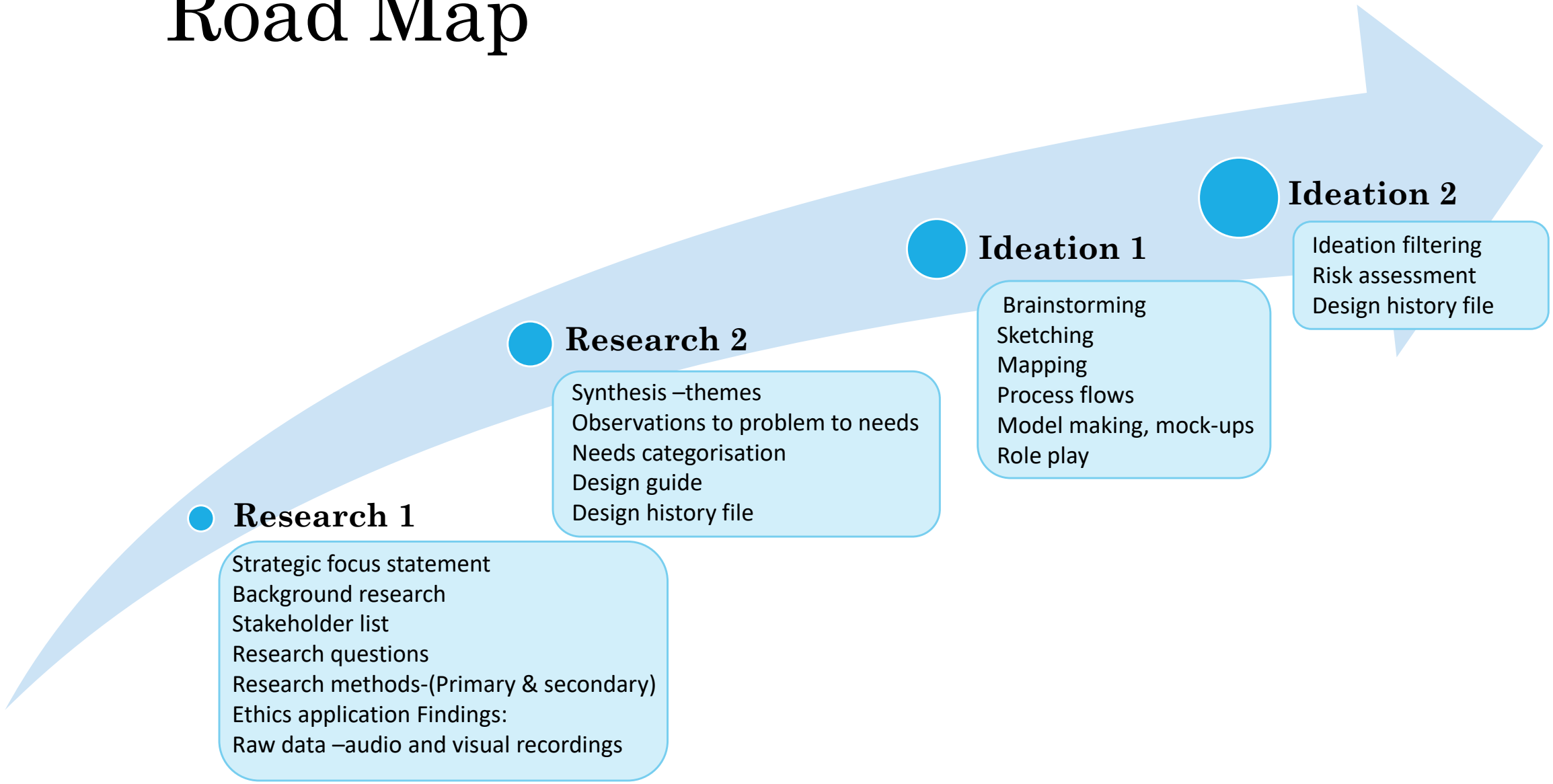
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Speculum?

- This first part explains what a speculum is and what it is used for.

What is a speculum used for?

- The physician performs the clinical examination at the speculum in the case of annual checks to observe the internal walls of the body. The doctor checks for colour, appearance, suppleness, the presence of a lesion or bleeding. This examination is carried out in order to visualize the macroscopic appearance of the cervix and the vaginal mucous membrane as well as cervico-vaginal secretions and to take samples.

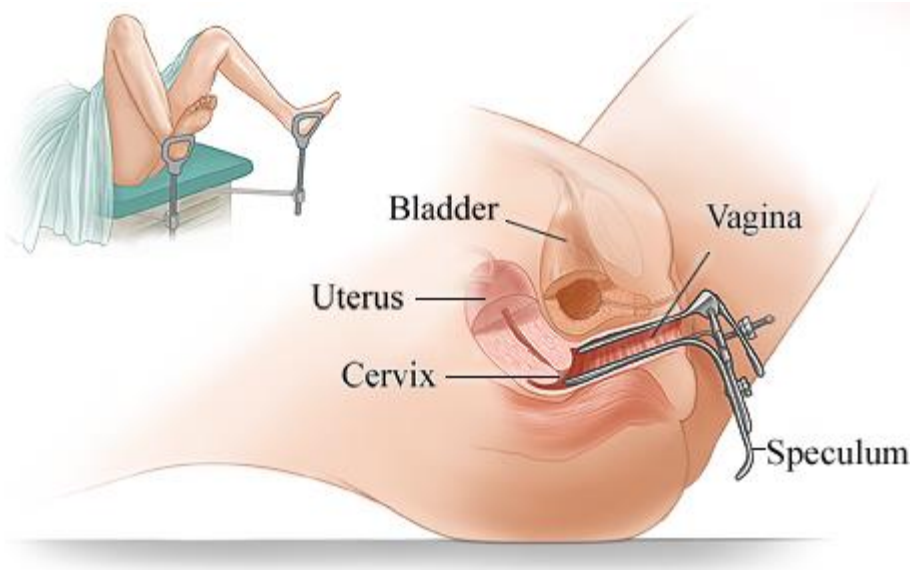
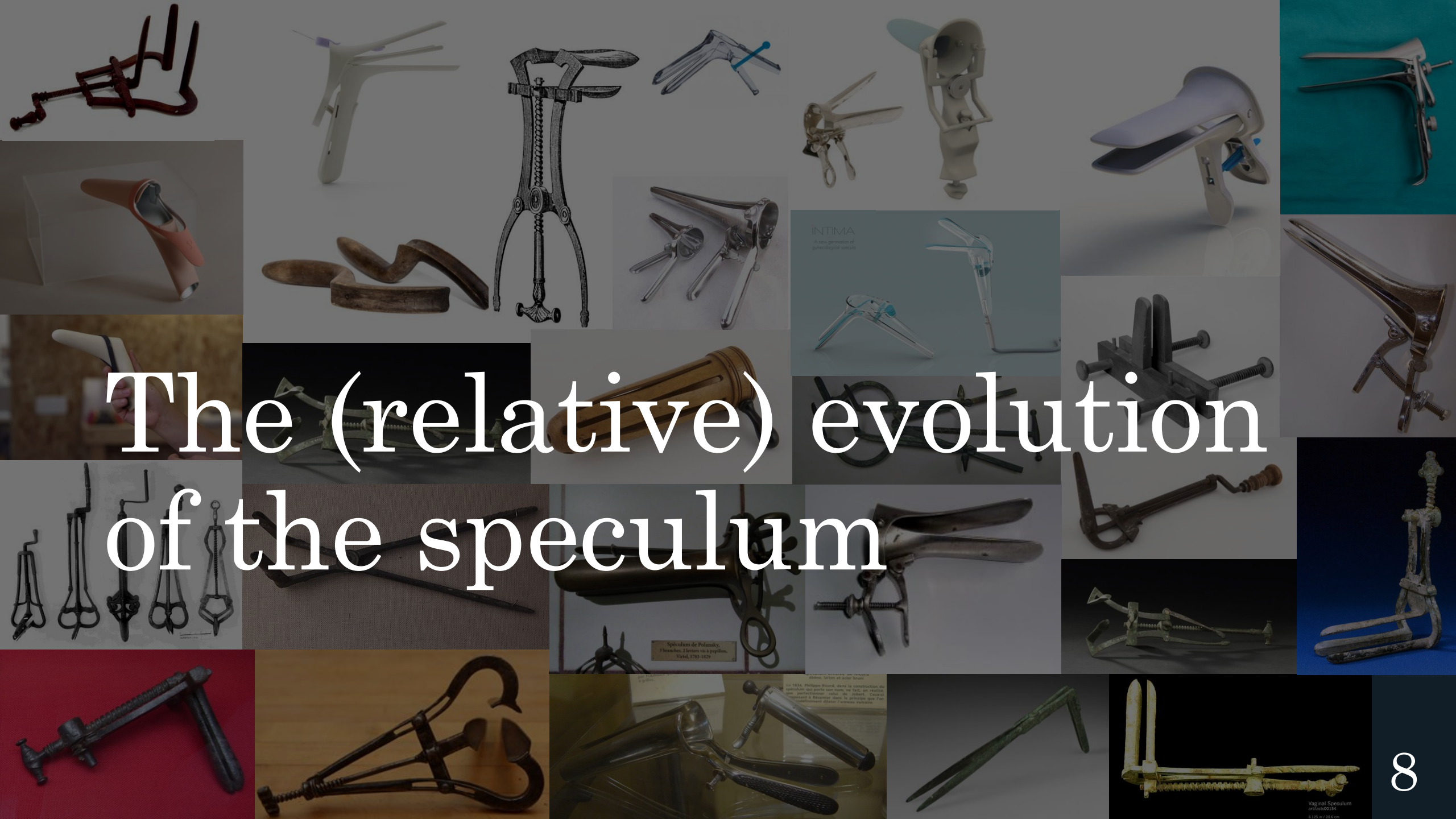


Fig.1 Cross-section of a gynaecological observation

What is a speculum used for?

- The speculum examination makes it possible to:
- 1. Highlighting macroscopic vaginal and cervical lesions that are infectious, traumatic or tumorous.
- 2. Assess the opening of the external cervical os and the quality of the cervical mucus.
- 3. Determining the origin of genital bleeding
- 4. Highlight the existence of leucorrhea which can be sampled
- 5. Take bacteriological samples in the event of any suspicion of infection.
- 6. Perform a cervical screening test (smear test)
- 7. To reveal the existence of bluish nodules in the posterior vaginal, suggesting endometriosis of the recto-vaginal septum.



The (relative) evolution of the speculum

The (relative) evolution of the speculum

- **Introduction**
- Before beginning this part, I would like to make it clear that this is by no means an in-depth study of the technological developments brought to the speculum over the centuries up to the present day.
- Nor do I wish to criticise in any way the work done by hundreds of engineers and inventors before me.
- This part is simply intended to provide more clarity on the origin of the speculum and also to show the historical significance of this nearly two thousand year old medical instrument.

The (relative) evolution of the speculum

- The word speculum comes from Latin and means mirror and is also expressed by what is used to see. It has evolved into a more "modern" form since the one century meanwhile a specimen was even discovered in the ruins of Pompei.
- However, it is not only in Europe that such a technology was imagined, already in ancient Egypt traces of a trivalent speculum were found.
- With recent discoveries, it can therefore be established that the first speculum far resembling ours dates back to one century A.D. Jesus Christ.

Fig1. The speculum found in Pompei

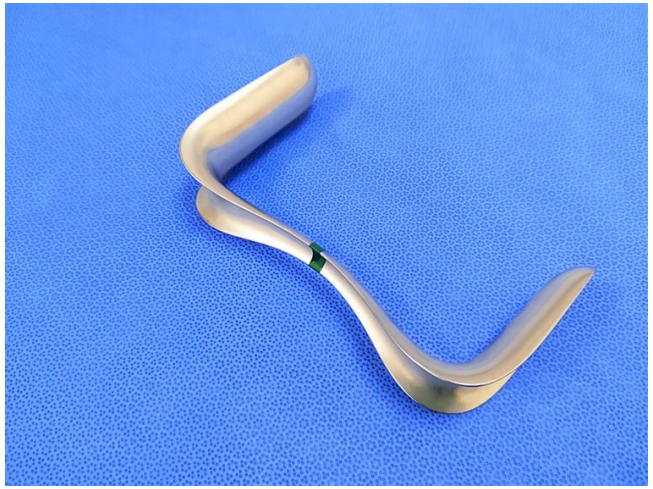
The (relative) evolution of the speculum

- The speculum continued to evolve during the Middle Ages and then also during the Renaissance throughout Europe, but the ideas were always focused exclusively on improving the visibility of the doctor and never for the comfort of the patients.
- Thus, many scientists such as Paul d'Egine or Ambroise Paré continue to propose new designs by welcoming new ideas such as the solid walls, the conical shape or the choice of material such as pewter while continuing to ignore whether the patient will be uncomfortable, stressed or bothered by these new speculums.

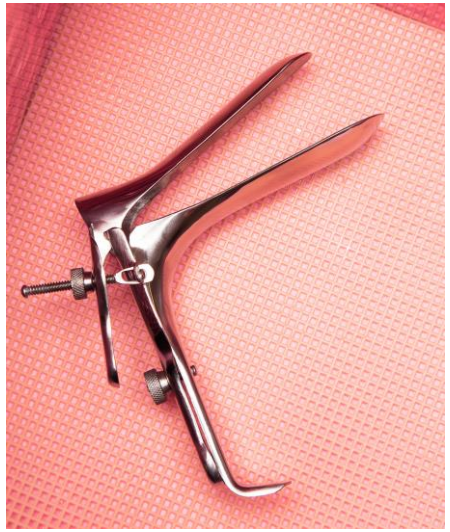
Fig.3 Récamier's speculum in 1818

The (relative) evolution of the speculum

- On the other side of the Atlantic, the speculum also evolved through the research of Dr. James Miron Sims in the 1840s. Sadly famous for having tested these different processes on black slaves without anesthetic and cold.
- The speculum then continued to evolve to resemble a duck's beak with a screw system to spread it out. It is now made of stainless steel or plastic with several different sizes depending on the morphology of the patients.



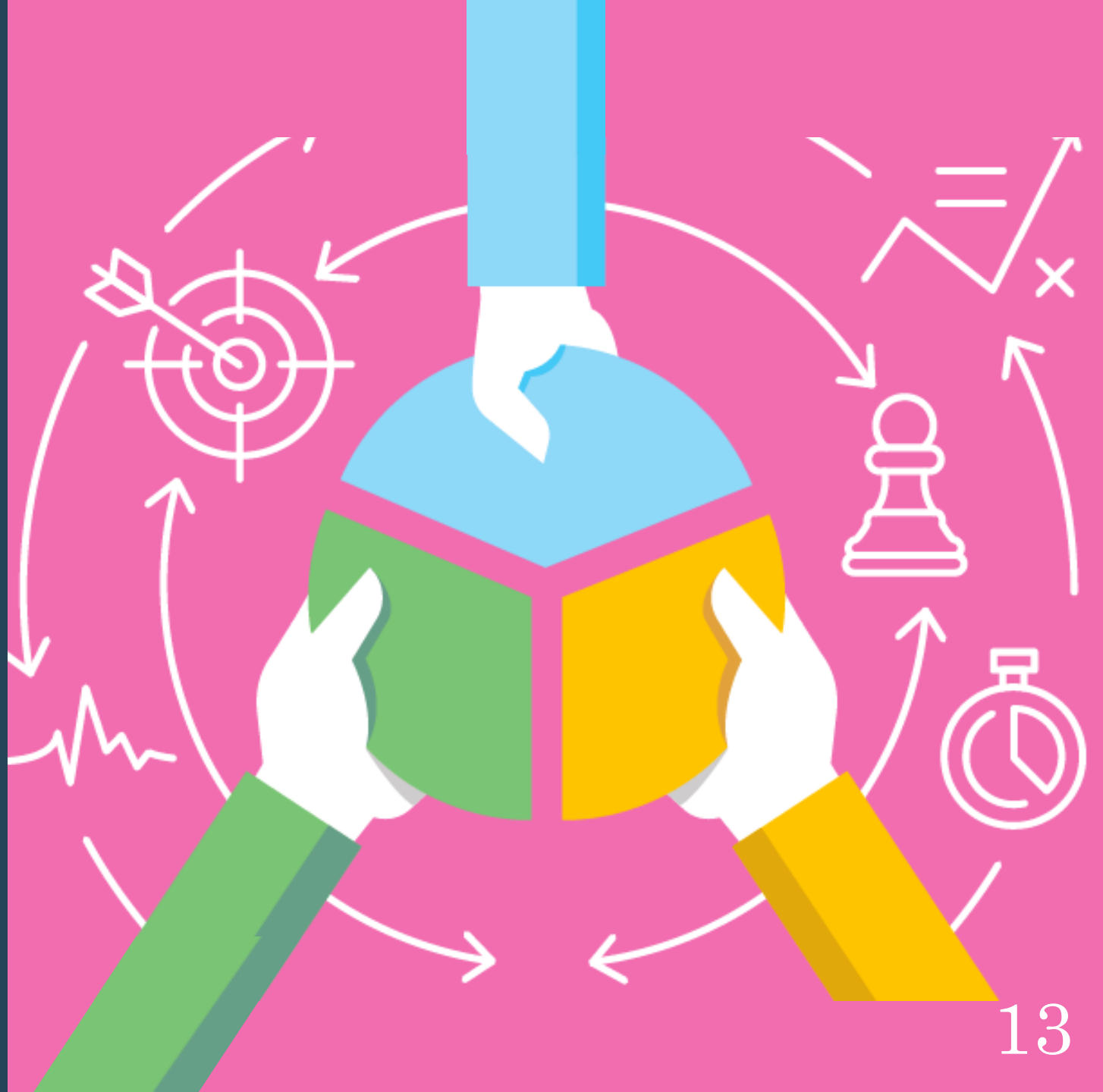
James Miron Sims's speculum



Modern speculum design

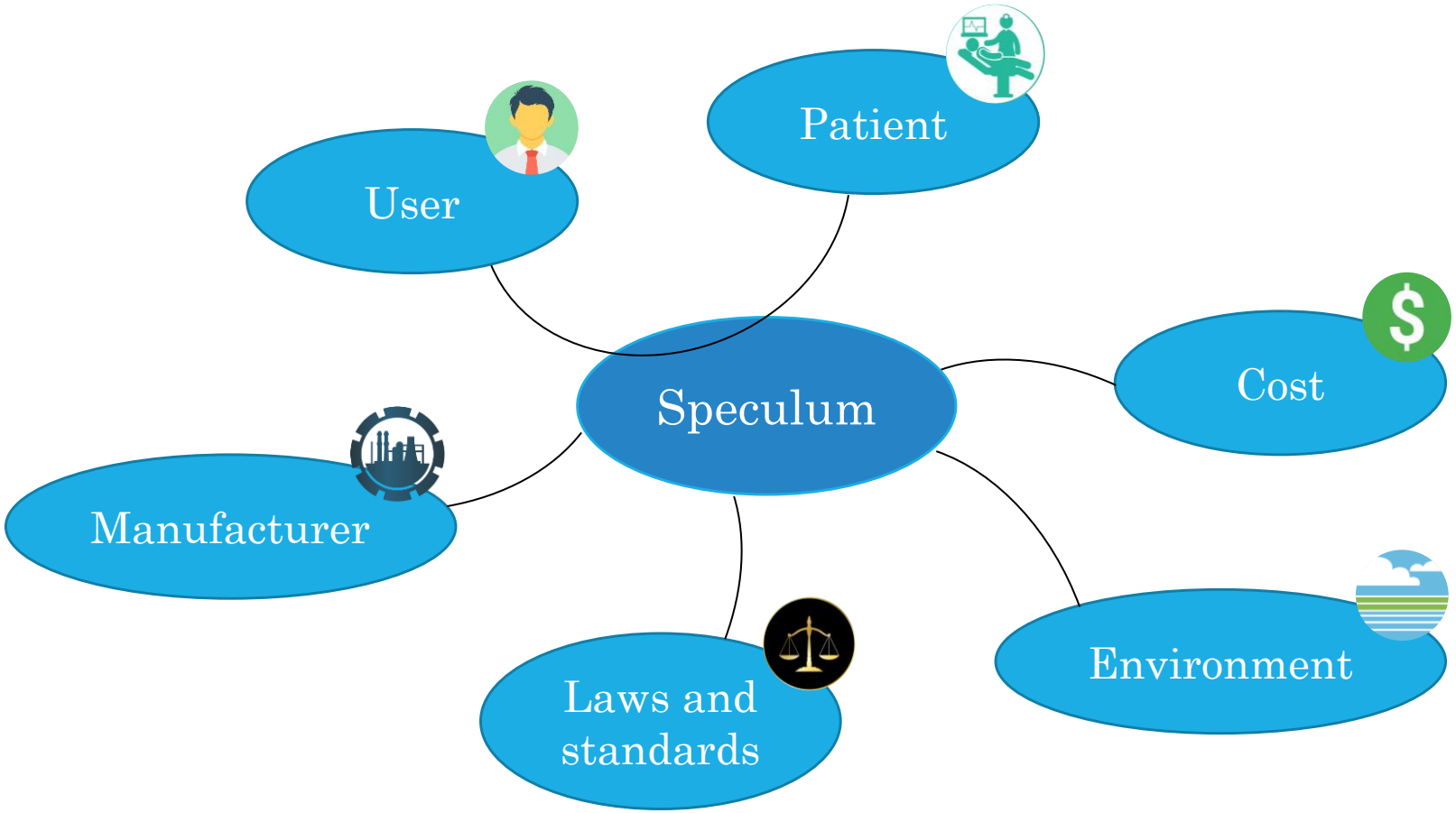
Stakeholders

- For this section, we will look at all the people who have a link with the product, both during its manufacture and its use.



Stakeholder list

Who interacts with the product?



Stakeholder list

Who are all these interactors?






USER	PATIENT	COST	ENVIRONMENT	STANDARD AND LAWS	MANUFACTURER
Gynecologist, surgeon, midwife Need to produce medical procedures and investigation	Women mostly around 15 to 65 Need to take care of their body	Director of hospital, maternity Need to respect a budget	Gynecologist, surgeon, midwife Need to produce medical procedures and investigation	Medical standard and laws Need to make people follow rules	Plastician, founder, industrial engineer Need to be able to produce the device

Research methods

- This part is dedicated to the methodology and research strategy to obtain maximum information on the speculum and its use.

Knows and unknowns

It exists two type of speculum (plastic and metallic)

There is an issue with the speculum for overweight's patients

Sterilization of the device needs a lot of time

It is used in surgery and for ordinary gynecologist procedures

What do patients think about the speculum?

What are the problems for clinicians?

Is there a lack of communication between patients and clinicians?

Do patients would like to do some procedures by their own?

Is there already new design on the market?

Does the new design should be single use or reusable?

What are the problems for patients?

Which improvements want both sides?

What are the prices for the different speculum?

Research methods

- Primary research
- This is based on two large pillars:
- -An online questionnaire
- -Online interviews
- The interviews aim to go beyond the questionnaire. And to look for the causes each time, a bit like the five whys method. Here, we don't just want to list the problems but to start finding the causes.
- Each of the interviews lasted about 30 minutes and highlighted that some problems were inerrant in the product or that sometimes only some people could endure difficulties. One of the problems I would take as an example is the allergy to the lubricant. It is rare but it can happen as I discovered through one of my interviews with a patient.

Research methods

- Primary research

- The interview with the medical staff is also very relevant and allows us to get a feel for the user's experience. Thus, for the creation of the specifications, I will have to find the right balance between the legitimate domains of the patients and those of the gynaecologists and surgeons. Concessions will therefore be expected during the various design productions for the new speculum.

Research methods

Who is going to be involved to obtain feedbacks?

- Patient List:

-20 women interviewed online with TEAMS

-100 women responding to an online questionnaire (Microsoft forms, in Annex 1)

- User List:

-Interview of gynecologist from the maternity of St John

-Interview of 2 gynecologist from France

This list is an objective, but it does not mean that the project cannot start if I do not reach the number of interviews noted above.

Research methods

- Secondary research

- As far as secondary research is concerned, there are two important points that I have focused on. The first was whether studies on patients' feelings about speculum procedures had ever been produced and if so, what the conclusions were.

- Finally, I also wanted to analyse the latest advances in speculum design so as not to be redundant in my ideas but also to soak up ideas that could help me in the ideation phase.

Secondary research

- This section is dedicated to an online search for documents providing information about patients' opinions on procedures involving the speculum, as well as on the technological advances it has undergone in the 2000s.

Clinician's experience from literature

- To begin with, I was interested in the basics, i.e., teaching clinicians how to perform the procedures requiring the speculum. I therefore looked at several books on the subject (Williams, A. A. & Williams, M. , 2013). I learned that future practitioners train on specialised standardised pelvic models, mannequins and patients.
- An interesting point is then raised by the author as indeed the only contact for students are specialised standardised patients, i.e., women who have chosen to participate in multiple PHEs with learners, and are therefore often free of extreme anxiety, sexual pain or pelvic disorders. These complicating factors are common in general practice but are not present in their training.

Clinician's experience from literature

- I then became interested in researching the speculum to improve procedures in collaboration with practitioners.
- The first one I discovered was the idea of no longer using the speculum for cervical cancer screening due to the stress and fear it causes in many patients (Asiedu et al., 2017).
- What is interesting about this study is the main idea of a tampon-sized insertion device and the POCkeT colposcope, a miniature pen-sized colposcope, for comfortable, speculum-free and potentially self-contained colposcopy.
- They eventually developed a probe-like insertion device as an alternative to the speculum for use with the POCkeT colposcope to image the cervix for cervical cancer screening.
- This study proves that it is possible to improve the existing product by truly taking into account the patients' feelings. However, it should be borne in mind that this type of equipment is limited to one type of procedure, whereas the speculum allows for a wider use.

Clinician's experience from literature

- Another particularly interesting study was based on improving the pelvic examination experience. Which is exactly what I was talking about by proposing a human-centred design (Taylor et al., 2017).
- I was initially reassured by the fact that they had identified the same main problems as I had, namely: anxiety, pain and discomfort (cold being present as a discomfort).
- They proposed an holistic approach (means to provide support that looks at the whole person, not just their mental health needs) base on three improvements: New approach to training of physicians, Revision to design of speculum, Incremental implementation.
- In theory, I should only be concerned with design issues, however the last point made is fundamental to bear in mind. The new design must also appeal to clinicians because they will be the users. Therefore, care must be taken to produce this evolution with them as well and not to abandon them for the benefit of the patients only, as otherwise they might stick to their beliefs (Rossman, 2008).

Patient's experience from literature

- I was first interested in whether there were already studies on how patients felt before and during speculum procedures.
- After reading a few dozen of them, starting with a French study (Freyens, 2017) which focused on the age group of young women, between 15 and 19. The study is interesting because it did not involve any women who had not undergone this type of examination but only asked them to describe the ideal examination.
- The study highlighted that the main need of future patients was to obtain knowledge of the procedure before undergoing it. This is consistent with my primary research.

Patient's experience from literature

- A second very interesting study, again from France (Million, 2020), sought to interview 13 women to analyse and understand the experience of French women during their first pelvic examination to propose practice recommendations based on their experiences.
- A Qualitative semi-structured interviews was conducted with these 13 French women aged 18–30 years recruited from the surgery of a general practitioner using the snowball method. The data were analysed using an inductive method.
- The results are also in line with my preliminary research because patients want someone who listens to them, who already has experience of the first examination for a woman.
- The examination would then be done in three phases:
- Before the pelvic exam where women and practitioners can get to know each other
- During the exam, which would involve the technical aspects and associated procedures
- After the examination, where patients and practitioners review the experience and discuss prevention.

Patient’s experience from literature

- There are additional studies that compare the patient's experience of the examination with that of the clinician.
- In this study (Bates, 2011) it was highlighted that this examination can be challenging for both and therefore requires close collaboration with the patient and a minimum of technical creativity, even the most difficult pelvic examination can ultimately be successful.
- This reinforces the idea of a project based on two clients, the patient and the clinician, both of whom must be satisfied with the new design while striking the right balance between patient comfort and examination efficiency.

Both experience from video interviews

- The video posted below is very interesting because it highlights the joint work of patients and clinicians.
- Here, a nurse takes care to explain the smear test with no taboos. Thanks to this interview, we discover once again that there is a lack of communication which is only due to fear, geine and sometimes lack of time during certain procedures.
- Patients are asked many questions before being examined, such as what they wear, whether they should shave or not. Questions that may seem anodyne, but when added to the stress of the procedure, make things worse.
- Therefore, I am certain that there is a need for maximum awareness of the various procedures involving the speculum to reduce stress and thus improve patient comfort, while facilitating the work of clinicians.

Both experience from video interviews

- Une nouvelle fois, une influenceuse à fait la démarche de se filmer Durant son smear test, le but étant de rassurer les femmes sur cette procedure.
- Ce genre de vidéos rencontre un franc succès sur les reseaux sociaux car elles peuvent être facilement partagées et propagées sur le net.

Benchmarking

- This section is dedicated to show actual vaginal speculum use on the market and show differences between the most used.

Actual providers

- Sklar Surgical Instruments
- CooperSurgical Inc
- Medline Industries
- WELCH ALLYN
- Teleflex Incorporated
- Becton, Dickinson and Company

Actual products on the market

- Below, I have produced a list of speculum available on the market. This list is not exhaustive and is only there to show the differences in design.
- It does however highlight that despite the different uses, there are few major differences in design between them.

Vaginal speculum from Sklar

Surname	Cusco
Tip Dimensions	3-3/4" x 1-3/8" Blades
Size / Model	Large
Material	Stainless Steel with Non-Conductive Coating
Disposable or Reusable	Reusable
Sterile or Non-Sterile	Non-Sterile
Latex or Latex-Free	Latex-Free
Add-on features	Smoke evacuation
Price	65 dollar

Vaginal speculum from Cooper surgical

Surname	Graves Specula
Tip Dimensions (mm)	W22-35 L87-125
Size / Model	Small, Medium, Large,
Material	Stainless steel
Disposable or Reusable	Reusable
Sterile or Non-Sterile	Sterile
Latex or Latex-Free	Latex-free
Add-on features	Integrated smoke tube
Price	12 dollars

Vaginal speculum from Cooper surgical

Surname	VU-More
Tip Dimensions	W33-35 and L93-180
Size / Model	Mini, Medium, Large, X to 4X large,
Material	Stainless steel
Disposable or Reusable	Reusable
Sterile or Non-Sterile	Non-sterile
Latex or Latex-Free	Latex-free
Add-on features	25% larger than usual
Price	10 dollars

Vaginal speculum from Medline

Surname	Pederson Vaginal Speculums
Tip Dimensions	W24-30 L88-125
Size / Model	Small, medium, large
Material	Stainless steel
Disposable or Reusable	Disposable
Sterile or Non-Sterile	Non-Sterile
Latex or Latex-Free	Latex-free
Add-on features	Narrower blades
Price	9 dollars

Vaginal speculum from Welch Allyn

Surname	KleenSpec
Tip Dimensions	Unknown
Size / Model	Extra small, Small, Medium, Large
Material	Plastic
Disposable or Reusable	Disposable
Sterile or Non-Sterile	Sterile
Latex or Latex-Free	Latex-free
Add-on features	White Led light source for 80 min of time
Price	2,34 dollars

Vaginal speculum from Teleflex

Surname	Graves vaginal speculum
Tip Dimensions	W33-37 L90-110
Size / Model	Medium, Large
Material	Stainless steel
Disposable or Reusable	Reusable
Sterile or Non-Sterile	Non-sterile
Latex or Latex-Free	Latex-free
Add-on features	
Price	15 dollars

Vaginal speculum from BD

Surname	O'Sullivan-O'Connor vaginal speculum
Tip Dimensions	W30-44 L90
Size / Model	Normal
Material	Stainless steel
Disposable or Reusable	Reusable
Sterile or Non-Sterile	Non-sterile
Latex or Latex-Free	Latex-free
Add-on features	Separate blades
Price	200 dollars

Vaginal speculum from BD

Surname	Graves speculum with suction
Tip Dimensions	W35 L114
Size / Model	Normal
Material	Gold plated; Stainless steel
Disposable or Reusable	Reusable
Sterile or Non-Sterile	Non-sterile
Latex or Latex-Free	Latex-free
Add-on features	Smoke evacuation
Price	73,10 dollars

Modern ideas of design on the market

- Since the 2000s, several companies have sought to redesign the speculum with ever innovative ideas. One of them was the use of an inflatable system to overcome the singular noise of the speculum and the temperature problem of the cold metal. Several patents have been filed as shown in the images below without these inventions finding real market outlets.

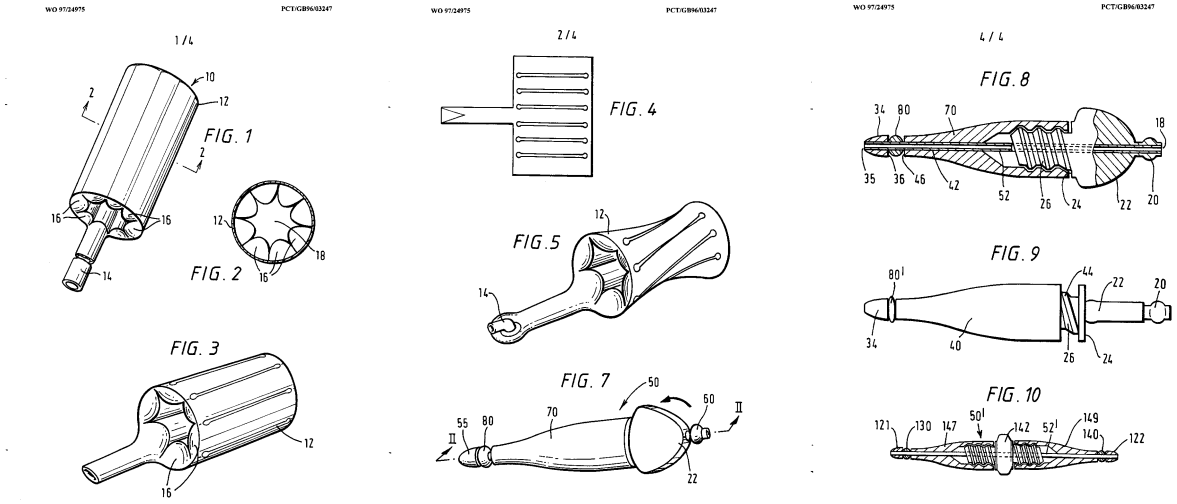


Fig.4 Drawing of a Bret for an inflatable speculum

Modern ideas of design on the market

- *Inflatable speculum*

Advantages	Disadvantages
New concept design	Too expensive
More comfortable for patients	Not easily sterilizable
Avoidance of strange mechanical noise	Hasn't been tested on women yet
Sterilizable	The gynecologist can't see sizes
	The device makes a strange sound when it is inflatable
	Maybe less strength than the human body to keep inflatable

Modern ideas of design on the market

- Another modern invention comes from Mercy Asiedu at Duke University in the United States. In 2019, she invented a product called Callascope to enable the early detection of cervical cancer with a simple and inexpensive product.
- This product has a tube to penetrate the vagina with outer walls made of plastic while the inner walls are made of stainless steel. Equipped with a camera connected by a cable to a smartphone, this system is capable of taking pictures inside the vagina to determine whether or not there is any uterine cancer.

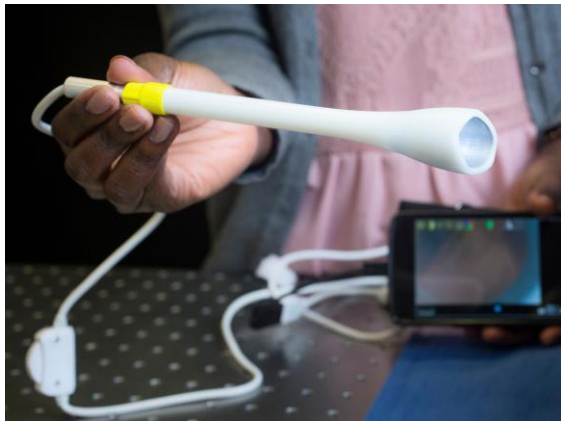


Fig4. Picture of the Callascope

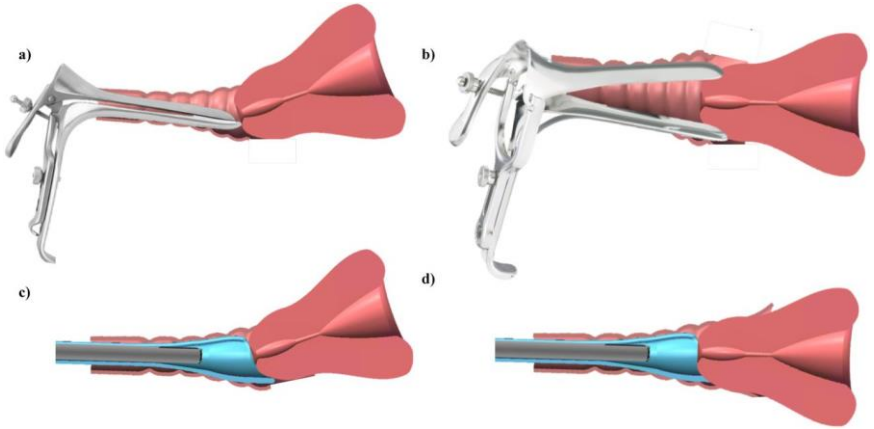


Fig5. Difference between using a traditional speculum and the Callascope in view of cutting

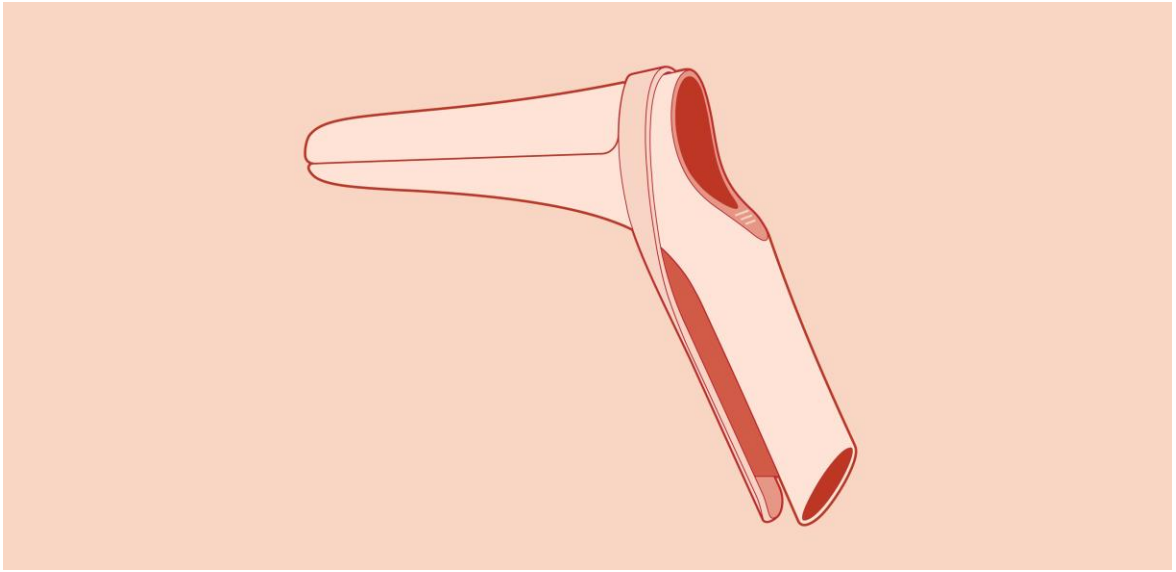
Modern ideas of design on the market

- *Callascope*

Advantages	Disadvantages
Cheap solution regarding the market	Can only take pictures of the servec!
Only needs a smartphone to work with	
Less uncomfortable than a normal speculum	
Good vision of the cervix	

Modern ideas of design on the market

- The idea came from two American designers who had been examined by a gynaecologist the same week. They then became aware of the need to revise the design but also the communication around the examinations requiring the speculum.
- The team also takes in mind that some people with a vagina doesn't identify as a female. Due to this, they take care of interviewing and discussing with LGBT community to identify some problems that they can have during pelvic procedures.



Modern ideas of design on the market

- *Yona speculum*

Advantages	Disadvantages
Take in accountant all genders	Expensive
Doesn't make any mechanical noise	Hasn't been tested on women yet
Is not cold	
Easily sterilizable	

Modern ideas of design on the market

- In 2020, the company Ceek Women Health women several awards as the TIME BEST INVENTIONS of 2020. They designed the Nella NuSpec which gives 2 essentials improvement:
- 1. A way better comfort for women
- 2. A better visibility for clinicians
- One of the main point of this new design is the Integration of sidewall retractors which keep sidewall tissue out of the way for more efficient exams and procedures.
- There are also other benefits as no lubricant required, one-handed locking, quiet and easy reprocessing.

https://vimeo.com/421745734

Modern ideas of design on the market

- *Nella NuSpec*

Advantages	Disadvantages
Pushes back the edges of the vagina so that you always have good vision.	Expensive
Can be use with single hand	Hasn't been tested on women yet
A light can be plug-in easily	
Locking system to allow one-handed operation	

Research questions

- The research is based on 5 questions would need to be answered throughout the project.
- Why do we need a speculum?
- What are the main issues / needs with the speculum for patients?
- What are the main issues / needs with the speculum for gynecologists?
- What are the main issues / needs with the speculum for surgeons?
- How is it possible to create a balance between patient and user needs for the new design of the speculum?
- Are there issues that occurs only for specifics types of person (obesity, transgender, …) ?

Primary Research

- This section is presented to show the information gathered from the patient and clinician interviews and the online questionnaire.

Raw data from Patient's interview

Nb.	Questions	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7	Patient 8	Patient 9	Patient 10	Patient 11	Patient 12	Patient 13	Patient 14
1	Have you ever experienced a procedure with a speculum?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2	How old are you?	22	22	26	30	24	27	28	29	26	24	23	31	27	24
3	At what age did you undergo a procedure involving a speculum?	16	15	15	17	14	15	15	16	16	17	23	22	19	20
4	What was the reason?	Consultation to obtain contraception	Annual checking	Annual checking	Consultation to obtain contraception	Annual checking	Consultation to obtain contraception	Annual checking	Consultation to obtain contraception	Consultation to obtain contraception	Annual checking	IUD coil insertion	IUD coil insertion	Annual checking	Consultation for anormal bleeding
5	In advance to having the procedures, did you understand what it would envolved?	No	No	A little bit	No	Yes	A little bit	No	Yes	No	A little bit	Yes, because I studied it and also on google	A little bit	No	No
6	Did you feel stress before the procedure?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes, really stressed and she took tablets to be less stressed	Yes	Yes	Yes and even more after googling it
7	If so, what was the reason for this?	Fear of being naked in front of a stranger	Fear of the unknown	Fear of the discomfort	Fear of the unknown	Fear of being naked in front of a stranger, fear of the pain	Fear of being naked in front of a stranger	Fear of the unknown	Fear of being naked in front of a stranger	Fear of being naked in front of a stranger	Fear of the unknown, mainly the disconfort	Fear of being naked in front of a stranger, fear of panic	Fear of the unknown, Fear of panic	Fear of pain	Fear of pain
8	Were you happy about the explanations given before the procedure involving the speculum?	No	No	Yes	No	Yes	No	No	Yes	No	No	No, I wasn't really called anything	Yes, the gynecologist explained everything in details	No	Yes
9	Were you happy about the explanations given during the procedure invovling the speculum?	No	No	No	Yes	Yes	No	No	No	No	No	Quiet yes	Yes	No	Yes

Raw data from Patient's interview

Nb.	Questions	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7	Patient 8	Patient 9	Patient 10	Patient 11	Patient 12	Patient 13	Patient 14
10	How many times have you gone through a procedure involving a speculum?	2 times	At least once a year	At least once a year	Dozen	Four times	At least once a year	Dozen	At least once a year	At least once a year	3 times	Twice	Dozen	Dozen	2 times
11	Did you experiences any of theses followings during the procedure?	Discomfort, cold, stress	Cold, stress	Discomfort, cold, pain, stress	Discomfort, cold, stress	Discomfort, cold, strange metallic noise	Discomfort, cold	Discomfort, cold, stress, pain	Cold, stress, srange mechanic noise	Discomfort, cold, pain, stress	Discomfort, cold, stress	The sound was really weird, cold	Cold and discomfort due to the strange metallic sound	Cold and discomfort due to the strange metallic sound	Discomfort and coldness
12	What improvements would you like to see made to the speculum?	Have a product more confortable, hotter, looks gentler	Have a hotter product, softer material, looks gentler	Have a product more confortable, softer material, looks gentler	Have a product more confortable, hotter, softer material, looks gentler	Have a product more confortable, hotter, softer material, looks gentler	Have a product more confortable, hotter, softer material,	Have a product more confortable, hotter, softer material	Have a hotter product	Have a product more confortable, softer material, looks gentler	Have a hotter product, look gentler	The shape should open more naturally. Come inside small and then get bigger inside of it. It should have the shape of the vagina and not the form of a duck.	Have a hotter product and silent	Avoid the strange metallic noise and make the procedure quicker	Have a hotter product
13	Please ellaborate if you have any other comments about what you would like the speculum to be.	The speculum at the same temperature than the patient	The design of the speculum should be more a tube than a duck face	The metal material should be discarded	A way to make the procedure quicker.	It is important to keep different sides of speculum	The speculum doesn't need to look nice. It just needs to be nice.	A way to make the procedure quicker.	Think about people who are allergic to vaseline		A way to make the procedure quicker.		A smooth and hot speculum which could take the space of the vagina would be great		
14	If it was possible, would you like to conduct minor procedures like smear test at home by yourself?	Yes	No	Yes	No	Yes	No	No	No	No	No	Yes, but only for smear test	No	No	No
15	Have you other comments to add?	It was really traumatic		It was really traumatic						It doesn't need to look nice but it needs to feel nice		I was expecting the coldness and the discomfort, the position wasn't confortable			

Profile of clinicians interviewed

- Doctor 1: consult, gynecologist, obstetric for 24 years and 10 years as a trainer
- Doctor 2: 12 years as gynaecologist and consultant for 1 year
- Doctor 3: gynecologist, obstetric for 8 years
- Doctor 4: Surgeon for 20 years
- Doctor 5: Surgeon for 15 years
- Doctor 6: 16 years as gynaecologist and consultant for 7 years

Raw data from Clinician's interview

Nb.	Questions	Doctor 1	Doctor2	Doctor 3	Doctor 4	Doctor 5	Doctor 6
1	What are the main procedures which involves a speculum?	nearly every examinations	nearly every examinations as looking for prolaps, unusual bleeding	looking for prolaps, health of the vagina and the cervix (pre cancer)	Assesing bleeding in pregnancy , assessig cervix, woman in preterm laber , induction of laber, open the survec, dilapan induction of labber	nearly every examinations that they are doing in examination, vagina pain, msear test, biopsi	Nearly every examinations to investigate for all kind of issues (anormal bleeding, possibility of cancer, …)
2	Why the opening of the speculum is always vertical? Is there a utility?	Due to walls anterior and trucmush, it is the opening way of the vagina and it it is the best way to open it with the speculum			It is how muscles are, easily opening		Because it is the way of how the vagina opens
3	Do you need to see sides or only the front?	You need to sides also, prolaps or bleeding to investifgate and also infections			Menopose and bleeding need to see sides for tissu, don't really need to be transparant because he turns it inside of it	It depends, of the test. Sometimes you need to see walls to inspect them to do an investigation.	The need is to have a perfecti vision of the cervix but walls can be also important. But no need to be able to operate on them with it.
4	Do you prefer reusable or single use speculums?	I prefer reusable because it is more ecologic but it demands a big organization for sterelization.	I use only single use speculum.	It depends of the quality of plastic for single use; they can break with overweight women, She loves transparent idea	Always single use speculums. The cleaning process takes too much time and maybe we will not have enough speculum	I don't really care. Pracitcal point is single use but ecological for reusable, chirurgien = reusable	Preference to the single use even if it is really bad for the earth because it creates even more pollution.
5	Do you always use lubricant ?	Yes, I never had an allergic patient.	Yes, always. Some of thel are allergic, only water if it is the case.		Yes. No one allergic, maybe one or two	Yes, I never had an issue with allergic people.	Yes, but he had three or four allergics women.For them, he used only water
6	What are the problems that you face?	A lot of my patients feel that the device is too cold and too hard. Sometimes, I don't have enough brightness during examinations.		Mainly when sides walls are coming inside, different size of speculum, probably 3 for virgin and menopause women, medium and occasionally long one	The screw one is the best because it is strong enough to use only one hand. (BMA index) Overweight women or women who had a lot of children are an issue for walls.	Sometimes, the side of the speculum. Hard to see anything. The walls that come inside of it.	He thinks that the needs of four different speculum size is an issue: small (for young and sexualy unactive women), medium, big and long
7	What are the things that you want to keep from the original speculum?	The fact that I can use it with only one hand due to the lick system.	I would like to keep it transparent.	The shape and round and the end, easely handy	Different sizes, medium and longer speculum and small speculum	I like the way where you can lock it in place. Only need 1 hand to use. Transparent	The use with only one hand is really important
8	Why you can't reuse the plastic one?	The problem is that for sterilization we put put the device at hight temperature and it won't be possible with a plastic speculum		Don't know, more healthy point of view	Easier to clean metal because the temperature is high	I have 40 patients everyday, which means that I would need 20 speculum.	Due to the sterilization cycle. It would degrades the plastic.
9	Do you have any idea of new design?	I would like of a speculum that could fit for all different size of vagina and not having 3 differents one.	A silent speculum that would open with a gentle system with a light inside of it.	A membrane inside the speculum to keep walls out. Isolate to not let the current pass, a light source throught it	It opens in 4 parts no thin parts like the new design. A transparent wall is not the solution to see properly walls.	Use of something elses than a plastic glove for protecting walls and a light inside of it.	A light would be a major improvement. Create one product for all size of vagina would be excellent but maybe hard to design.

Analyze of research

- This section is here to analyse and give conclusions regarding all information taken from primary and secondary research.

Analyze of secondary research

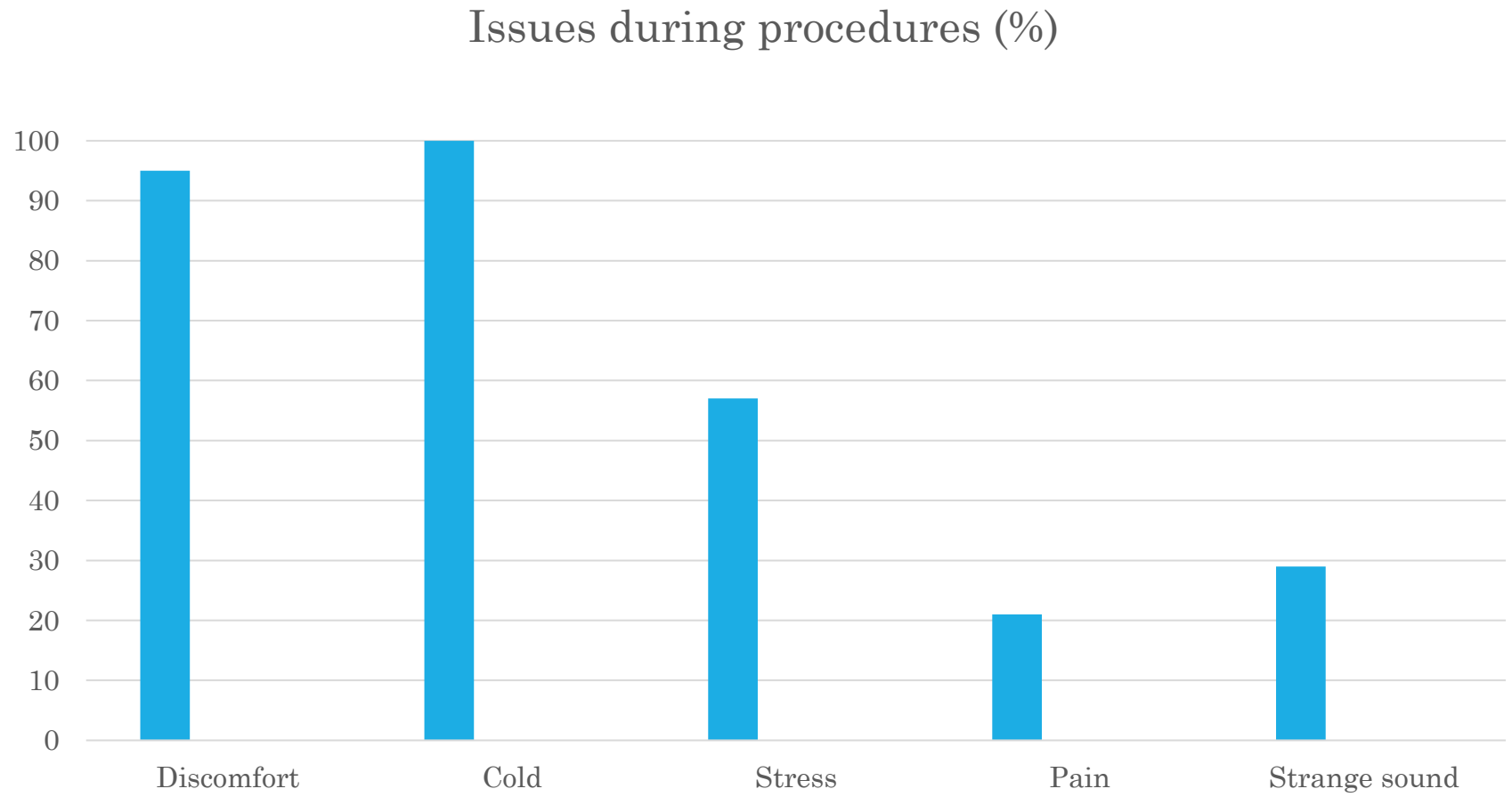
- After analysing the various inventions that have appeared since the 2000s, I quickly realised one thing, none of them have made a breakthrough. Most, if not all, of these inventions have remained at the patent stage and have simply been tested and then abandoned.
- Strange thing when you read and hear patients so easily criticizing this product. It is almost impossible to find a woman who defends the current design and yet none of the ideas that seemed interesting have managed to make it onto the market.
- So the problem would not come from the patients. If you think about it a bit more, it is easy to explain, they are not the buyers.
- They are not the purchasers, they are not the purchasers, so you have to look to the purchasers, which are the hospitals and gynaecologists' surgeries. If you take the time to talk to them and read the information in the newspapers, you quickly realise that most gynaecologists think that the current product is suitable for their use and that there is no need to change it.

Analyze of secondary research

- After becoming aware of this, I immediately understood why previous designs have failed or why others are still at the prototype stage.
- The problem was in their development, they did not try to get gynaecologists and surgeons to invent the product with them. Instead, they were content to design by simply observing a set of specifications, taking into account the legitimate demands of patients, but perhaps forgetting that this was first and foremost a medical device and who was going to use it.

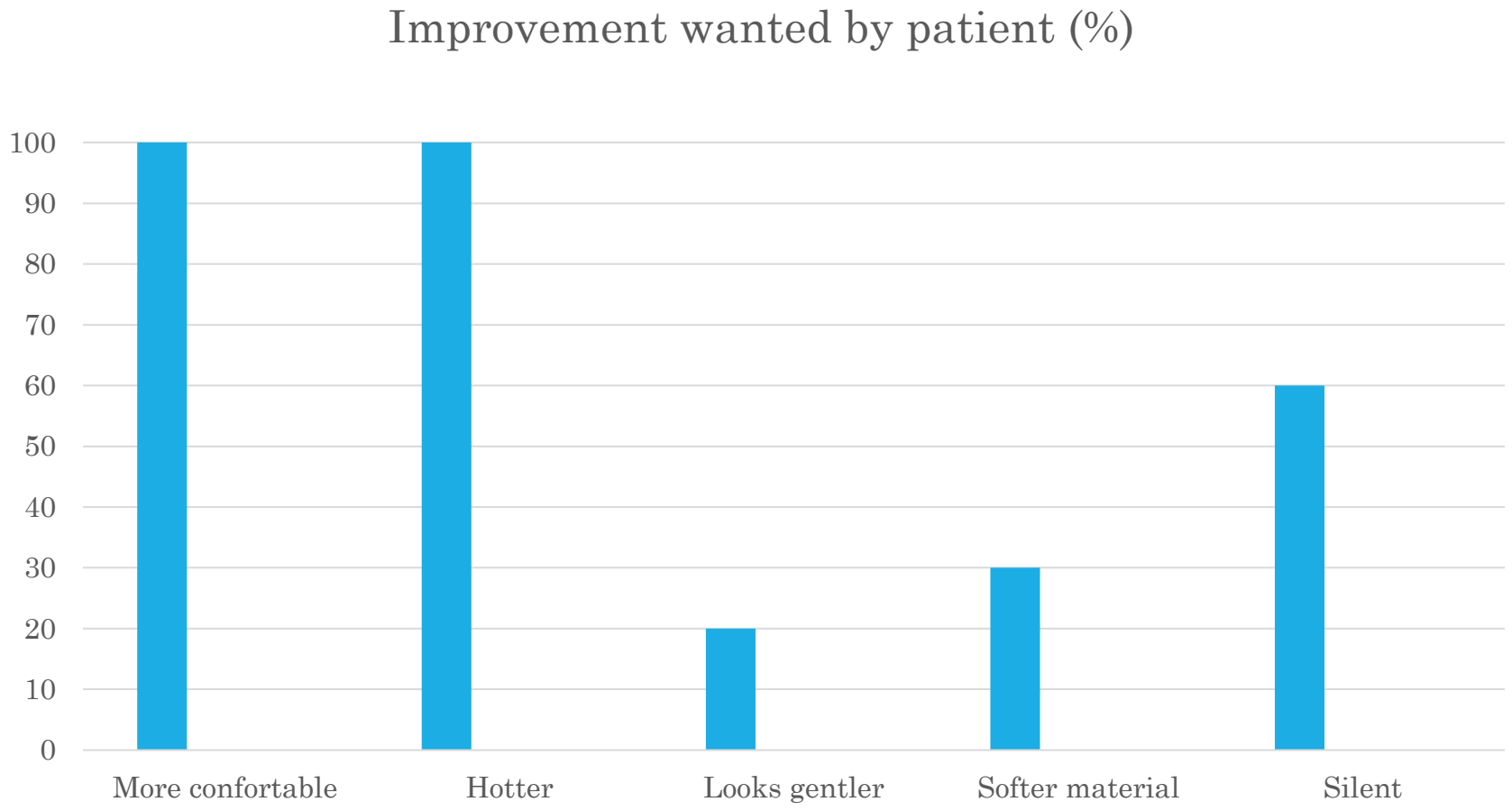
Analyze of primary research

- **Patient's interview**



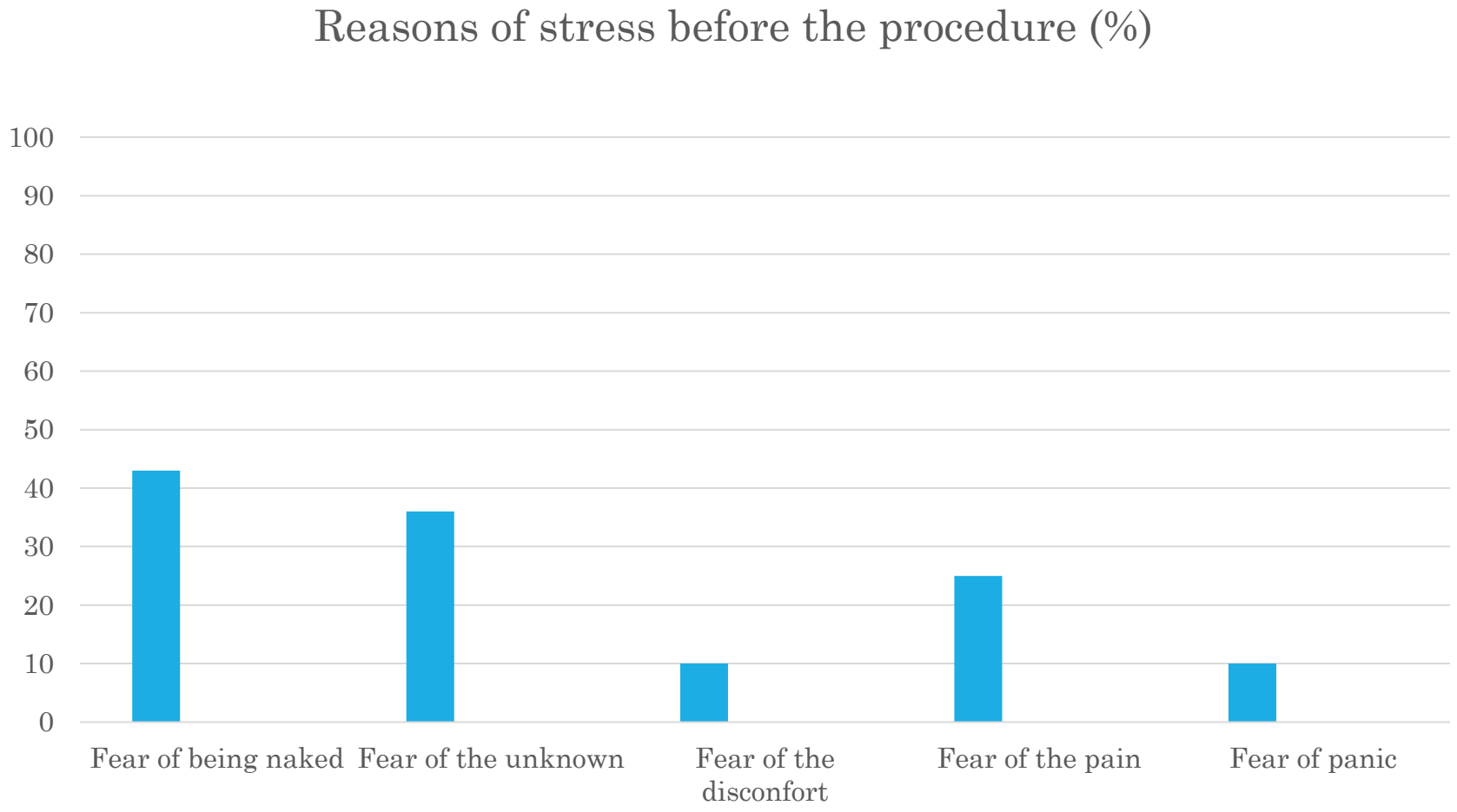
Analyze of primary research

- **Patient's interview**



Analyze of primary research

- **Patient's interview**



Analyze of primary research

- **Patient's point of view**
- Regarding interview of patient's, it is easy to say which are the key points which have to keep in mind during the elaboration of specifications.
- First of all, comfort and temperature are two points that should be kept in mind.
- As for fear before the procedure, an awareness of what the speculum is and what the procedure is, seems to me to be a good idea.
- In addition, these fourteen interviews brought out desires for a new product through ideas such as a speculum that would have exactly the same temperature as the human body or a soft material that would not shock the patient.

Analyze of primary research

- **Gynecologist and surgeon's point of view**
- The interview of six gynaecologists was very interesting, particularly because two of them are located in France and not in Ireland. Thus, I was able to discover that the problem of overweight patients is much more present in Ireland and England than on the continent.
- Subsequent discussions have established that when we talk about the speculum, we are really talking about two different products.
- One is for gynaecologists to inspect the vagina where they use a speculum of several sizes (three in total) made of transparent plastic. The second is made of metal, covered with blue plastic paint and is only available in two different sizes.
- One could then wonder whether the solution would not be to create a product to meet both needs, but this would mean forgetting the difference in needs that separates the two and which has yet to be precisely established.

Analyze of primary research

- **Gynecologist and surgeon's point of view**
- During the interviews, I was able to see the obvious, the product should be split in two as it is at present because of a second problem. This is that of sterilisation. Gynaecologists use a plastic one for a single use because they don't have the time or the means to send them to be sterilised each time between two procedures.
- So they need one for a single use and a second one that can be sterilised unless they simplify sterilisation to reduce this plastic pollution.
- Finally, with regard to the ideas that the gynaecologists had, the general opinion is really the protection of the walls by a wall or a pair of extra arms on the sides.
- As well as the provision of easily applicable light inside the speculum to facilitate the vision of gynaecologists or surgeons.

Observations

- The goal here is to list every observations to not loose any information to create the design guide.

List of observations

Patient point of view	Clinician point of view
All patients feel the product is cold	People allergic to lubricant are very rare
Most patients feel it is unconfortable	They need a good brightness to analyze the cervix
Some patients feel pain during procedures involving speculum	Most gynecologist face an issue with overweight women who has their vaginal walls which closed on the speculum.
Most patients are stressed before and during examinations	Gynecologsits need to use three sizes of speculum and sometimes four
Patients want to understand the procedure	Gynecologists prefer the single use speculum because to sterilize the speculum after each procedures would be a lost of time
Patients want to be involved in a new design	It exists one speculum for surgery and another one for examinations (metallic and the other transparant plastic)
Most patients don't like the mechanical noise of the screw	

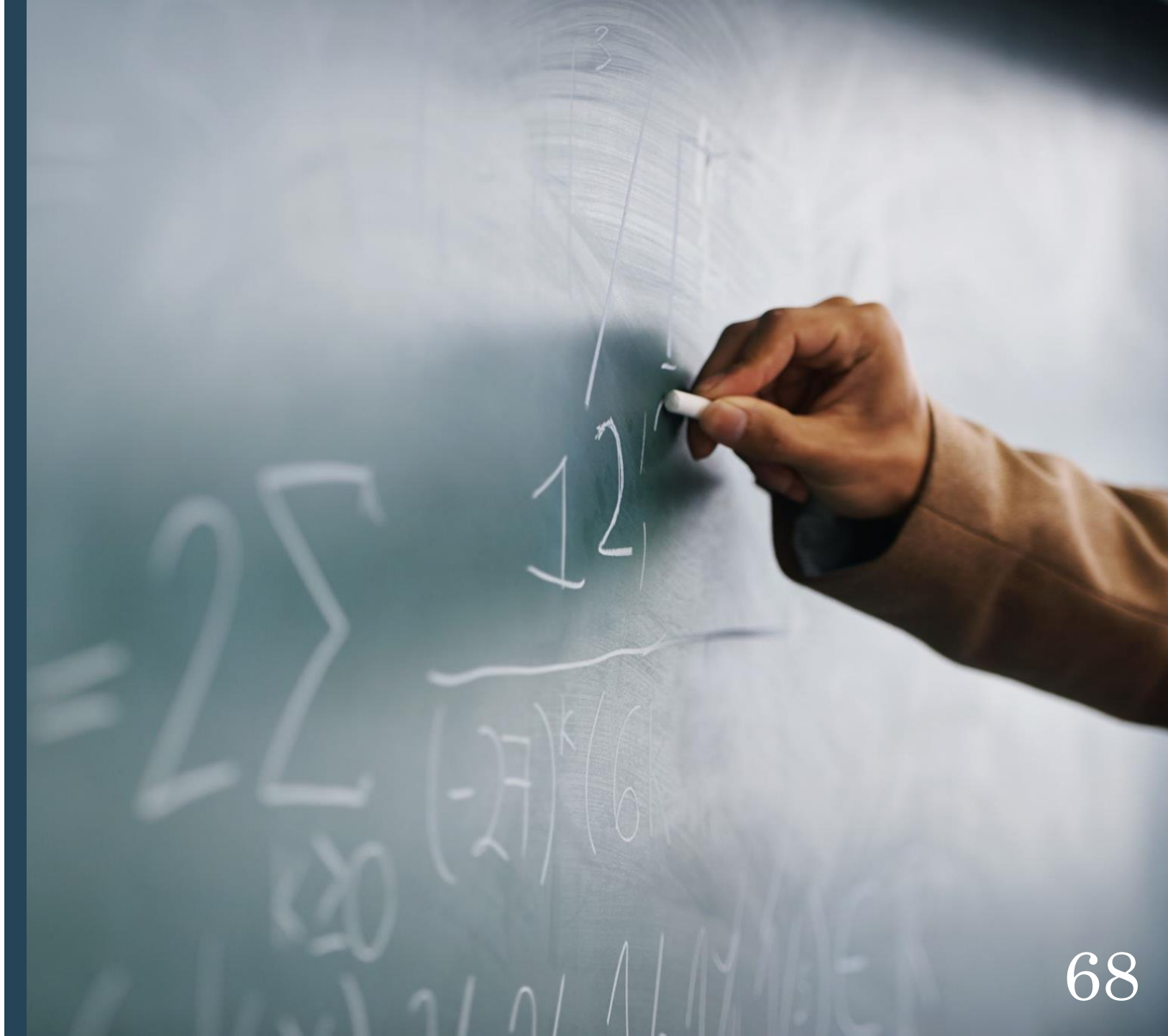
List of observations

- This list is separate because it does not concern the design of the speculum but the course of the medical procedure obtained thought the online questionnaire (All data are in Annex 2).

Patient's point of view
Patients say they lack information about how the procedure will be carried out
Patients have a lack of information about what is a speculum and how it will be used on them
Patients face stress before and during procedures
Some patients would be willing to do some procedures themselves
Some patients don't feel that they are enough listened by their gynecologist
Most patients would like to discuss the procedure with the gynaecologist before undergoing it

Problems

- Transformation of observations into problems



Observations to problems

Patient point of view	Clinician point of view
The product is too cold	A small amount of people can be allergic to lubricant
The products is uncomfortable	Clinician has sometimes not enough light
The product can occures pain during procedures	Most gynecologist face an issue with overweight women who has their vaginal walls which closed on the speculum.
Procedures create stress before and during procedures due to the lack of information	Gynecologsits need to use three sizes of speculum and sometimes four
Patients don't understand the procedures	Gynecologists prefer the single use speculum because to sterilize the speculum after each procedures would be a lost of time
Patients want to be involved in a new design	It exists one speculum for surgery and another one for examinations (metallic and the other transparant plastic)
The product creates a strange and unpleasant noise	

List of problems

- This list is separate because it does not concern the design of the speculum but the course of the medical procedure obtained thought the online questionnaire (All data are in Annex 2).

Patient's point of view
There is a lack of information for patients about how the procedure will be
Patients have a lack of information about what is a speculum and how it will be used on them
Patients face stress before and during procedures
Patients can't do some procedures themselves whereas they would like to.
Some patients don't feel that they are enough listened by their gynecologist
Most patients don't have the possibility to discuss the procedure with the gynaecologist before undergoing it

Needs

- Transformation of problems into needs

Problems into needs

Patient point of view	Clinicien point of view
Need to make the speculum at same temperature than the body	Need to give a source of light for clinicians
Need to have a more comfortable product	Need to prevent the walls of the vagina from closing in the beak of the speculum
Need to remove any sort of pain during procedures	Need to reduce the amount of different speculum sizes
Need to reduce the stress before/during procedures	Need to obtain a single use cheap product for clinicians
Need to make patients aware about how works the procedure	Need to obtain a sterizable product for surgeons
Need to involve patients into the new design	Need to have a product which can be used with a single hand.
Need to make a silent product	
Need to have a smoother product	Need to have visibility on sides of the vagina

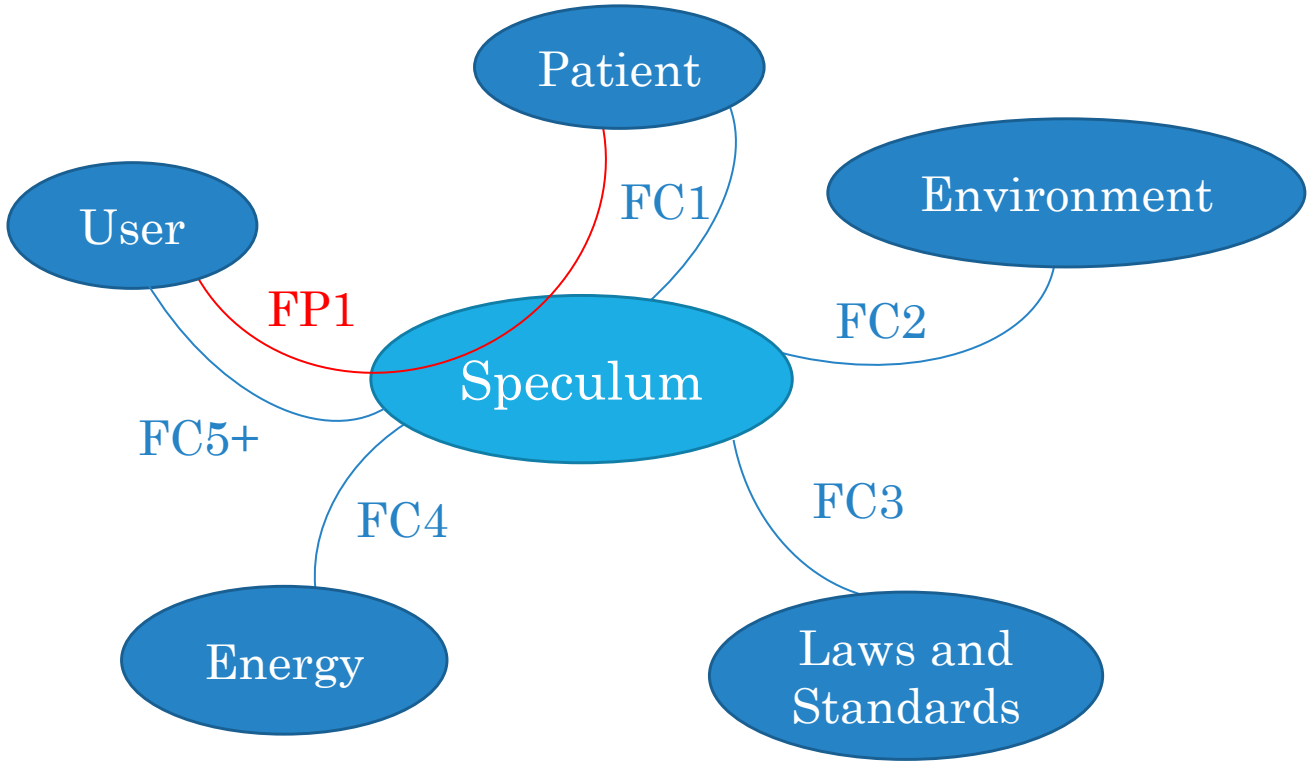
List of needs

- This list is separate because it does not concern the design of the speculum but the course of the medical procedure obtained thought the online questionnaire (All data are in Annex 2).

Patient's point of view
A way to give information for patients about how the procedure will be
A way to give information about what is a speculum and how it will be used on them
A way to reduce stress for patients before and during procedures
A way to allowed patients to do some procedures by themselves
A way to be sure that patients feel that they are enough listened by their gynecologist
A way to allowed patients to discuss the procedure with the gynaecologist before undergoing it

Needs categorisation

- Octopus diagram to analyze all the environment of the product:



FP = Function principal
FC = Function of constraint

Needs categorisation

Function	Definition	Criteria	Level	Flexibility
FP1	To enable clinician to see inside the vagina	Visibility Usability Brightness	As actual Single hand No need aditionnal device	F0 F0 F0
FC1	To be a more confortable product	Temperature Convenience Stress Noise	Body temperature Not painfull Acceptable Slight	F0 F0 F1 F2
FC2	To be the least polluting product possible	Carbon impact	C02	F2
FC3	To respect medical laws and standards	Laws and Standards	ISO13485, ISO62366	F0
FC4	To supply the device in energy	Energy	Electricity	F2
FC5	To prevent the walls of the vagina from closing in the beak of the speculum	Visibility	Vision of cervix	F0
FC6	To have as few different sizes as possible	Number	Less than 3	F3
FC7	To be easily sterilizable	Sterilizable	As actual	F3

Needs categorisation

- **Flexibility:** The flexibility of a function means how much the requested value or property must be respected. It can be translated as:
- F0: Non-negotiable (Must have)
- F1: Somewhat negotiable (Must have with modifications possible)
- F2: Negotiable (Nice to have)
- F3: Function possible but not mandatory (Nice to have with modification of level)

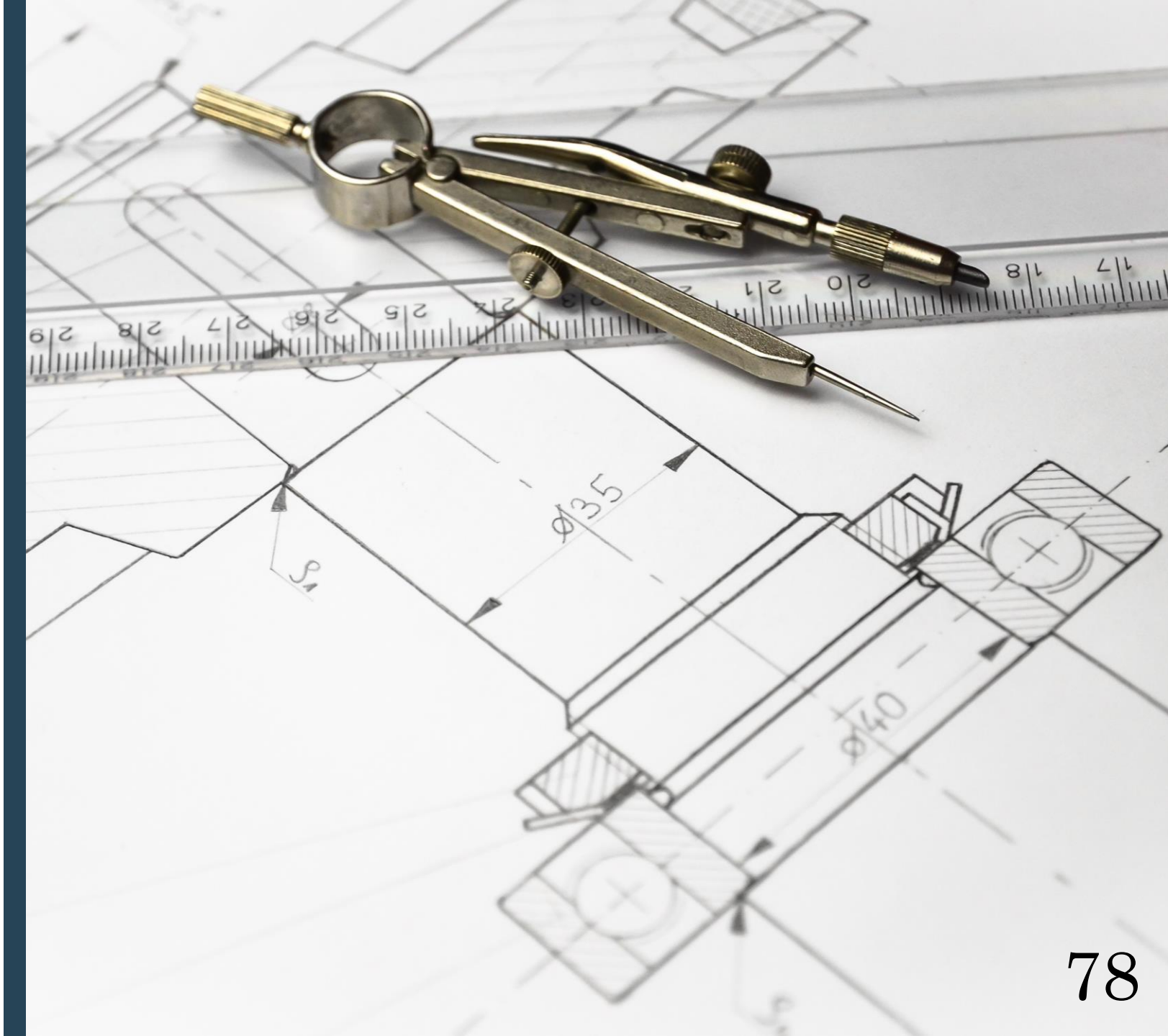
- This allows functions to be prioritised in order to best design a product that meets customers' needs.

Needs categorisation

- The purpose of this table is to produce what is known as a functional specification. It is omnipresent in product development in France.
- It provides a complete overview of what the product must be able to do while also notifying the constraints to which it must conform, such as standards or a third party user.
- These specifications must then be validated by the clinicians I interviewed to ensure that the project is going in the right direction by meeting the needs of the clinicians and also the patients.

Specifications

- This part serves to clearly define each function that the product must provide.



Specifications

- **FP1: To enable clinician to see inside the vagina**
- In the case of a visit to the gynaecologist, he or she must be able to observe the cervix, as well as the walls of the vagina, in order to carry out all kinds of investigations in the event of abnormal bleeding, painful periods, possibility of cancer etc.
- There are three criteria for assessing whether the product meets the need:
- Visibility (It must be at least as good as with the current product)
- Usability (It must be possible to use it with one hand)
- Brightness (Sufficient not to require the clinician to add an additional light source such as a headlamp)

Specifications

- **FC1 : To be a more confortable product**
- This is the opposite of the product's main purpose, which is to make it more comfortable for patients, based on four criteria that can be evaluated during the development of the new design:
- Temperature (Around that of the human body to avoid the sensation of cold)
- Convenience (Do not create pain and be as uncomfortable as possible)
- Stress (The design itself should not create any additional stress to its sight)
- Noise (It should not create mechanical noise like the current product)

Specifications

- **FC2 To be the least polluting product possible**
- This point refers to the high plastic consumption created by the use of a plastic product that has only one use before being thrown away.
- For this, I will use the carbon impact of the current product as a basis for seeking a new one with a lower final value.

Specifications

- **FC3 To respect medical laws and standards**
- This may seem obvious, but it is essential and will need to be analysed in depth to ensure that we create a product that can be sold on the market as medical equipment.
- Two particularly important standards to bear in mind when producing such equipment are ISO13485, ISO62366. The first concerns management, while the second concerns the rules for manufacturing medical equipment.

Specifications

- **FC4 To supply the device in energy**
- With the addition of a light inside the product almost a given, it is important to consider the management of electrical energy. However, it is not yet a question of providing a technical solution but simply of being aware that a solution will have to be found to supply the product with electricity.

Specifications

- **FC5 To prevent the walls of the vagina from closing in the beak of the speculum**
- This constraint meets one of the main needs of doctors, to prevent the walls of the vagina from closing in the beak of the speculum when observing an overweight woman.

Specifications

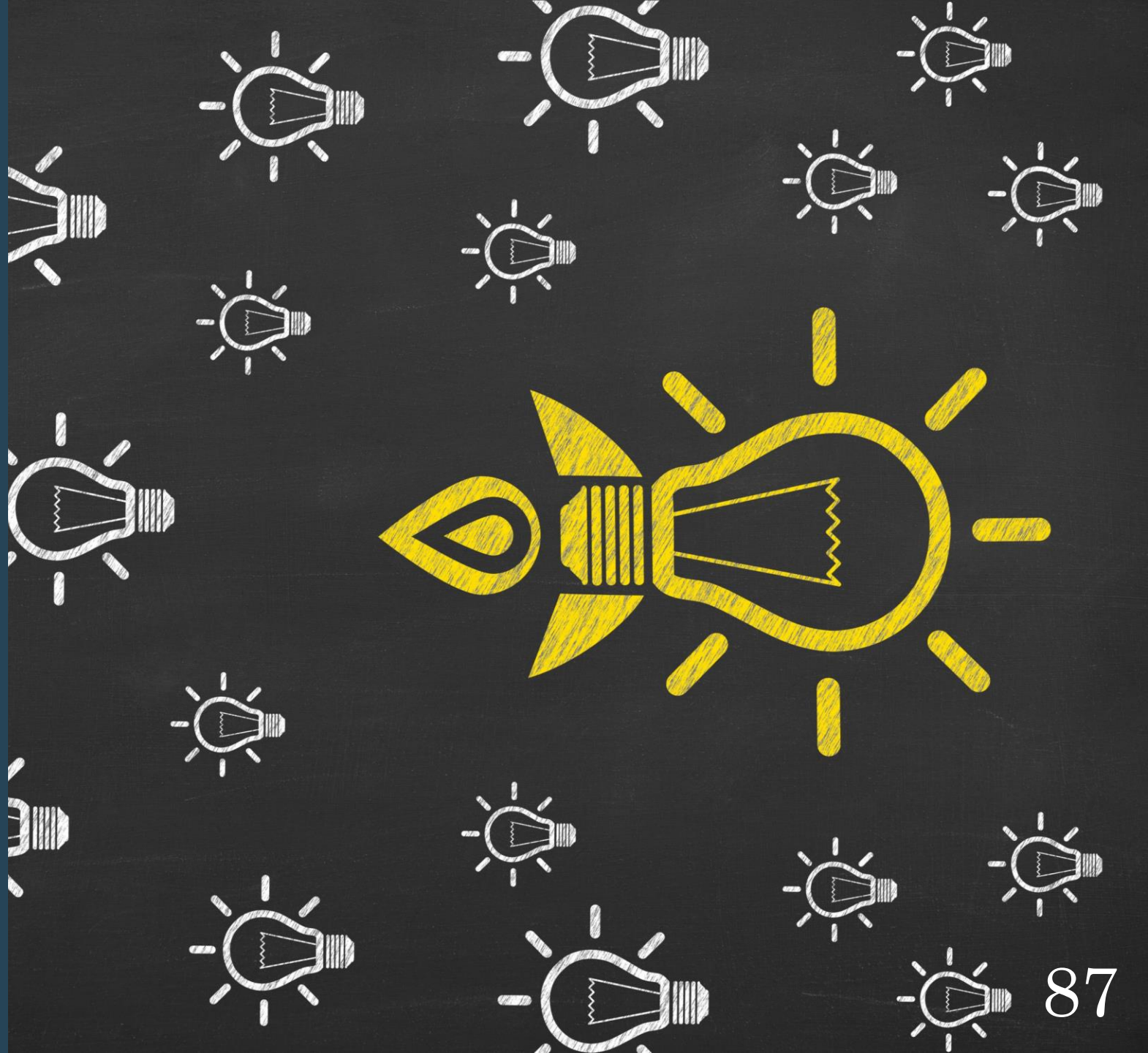
- **FC6 To have as few different sizes as possible**
- The current product has three different sizes at gynaecologists and even four at some centres:
- 1. The smallest for virgin or inactive women
- 2. Medium size
- 3. large size
- 4. Long size
- The idea here would be to be able to have a speculum that could be used on a wider range of women without making the procedure uncomfortable.

Specifications

- **FC7 To be easily sterilizable**
- The last constraint is one of the most negotiable because the easy solution to sterilisation is to have a product that is thrown away after the first use. However, in seeking to produce a new design that is more environmentally friendly than the current one, it is clear that the sterilisation solution would help reduce the carbon impact.
- However, this also requires additional work for the medical profession, which makes the solution to this constraint complex.

Brainstorming

- This part is there to share as many ideas as possible among the students to get as many as possible before thinking about choosing solutions for each need.
- This part could be defined as the blue-sky part.
- Each need will be brainstormed.



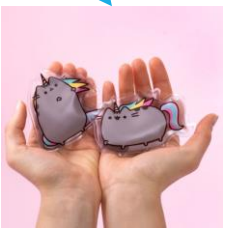
Brainstorming

- There is a need to make the speculum less cold

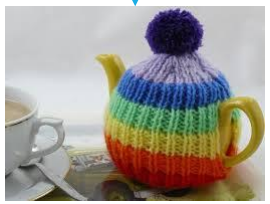
Slowly reduce the body temp. to reduce the shock

Use a warmer material

Self-heating speculum



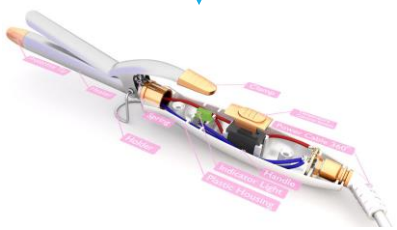
Inspiration from tea pot cozy



Heating gel in vaginal cavity

Make the procedure more gradual

Internal heating system



Brainstorming

- There is a need to make the speculum less cold

Work the breathing of the patient as for labor?

Preheat the speculum

Women use hot water bottles to ease cramps and provide comfort during period?

Elvie pelvic trainer

Make it soft and fuzzy

Special coating to preheat speculum

Use a hot lubricant

Insert with a balloon

Patients hold it in their hand first to acclimate to body temperature

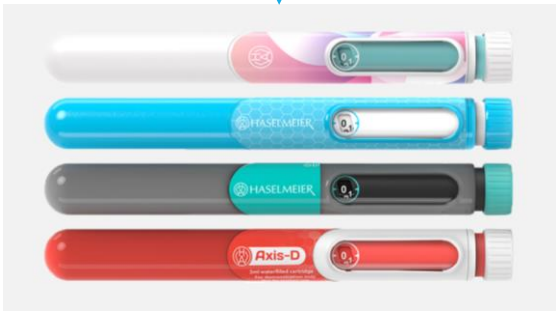
Create a system for own device and own speculum

Brainstorming

- There is a need to make the product less stressful

Show the product to patient before the procedure to discuss with her

Enable customized speculum (Cooper C., 2021)



Sell directly the speculum to each patients to break the myth

Avoid the metallic look

Avoid the strange noise

Discuss the procedure before/during/ after it.

Brainstorming

- There is a need to make the product more comfortable and not painful

Use softer materials

Have product that has the shape of the vagina

Have product that has the shape of the vagina

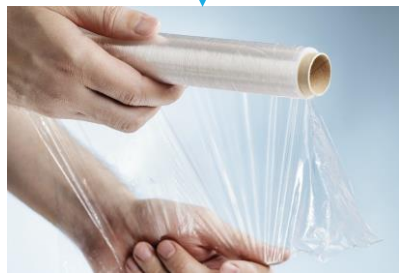
Have a slower and gentler penetration / opening

Have good different speculum sizes

Brainstorming

- There is a need to enable clinician to see inside the vagina

Transparant walls

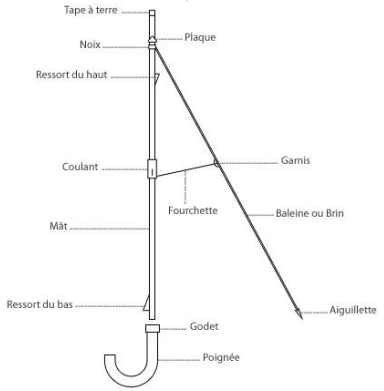


Additional blades

Change the system of opening of the device

Add a record camera

Umbrella system for opening



Add a ratchet wheel to facilitate locking the device

Add a small light

Change drastically the shape of the device

Ideation

- This part focuses on the main idea behind the whole project. That is, the strategy for bringing a new speculum design to the market.

Ideation

- One thing that came to mind was the fact that speculums were always bought by clinicians. This is not a bad thing in care, but it is what makes the device so stressful because it is mysterious in a bad way for patients.
- However, several movements in the 1970s led to activists in the US encouraging women to buy their own speculum (Daly, 1984). Others have even proposed that women perform self-monitoring of their cervix using a mirror (Anon, 1972).
- Without going from one extreme to another, I believe that the solution may lie in a speculum that is able to meet the needs of clinicians and patients while not suffering from the problem of price because, as I have shown before, disposable speculum prices will always be prized by hospitals when presented with another product that is ten times more expensive, even if it is more comfortable for patients and facilitates clinicians' procedures.
- Constrained by this money problem, I therefore decided to put on the table three viable strategies for developing new speculum design ideas.

3 Strategies

Disposable speculum own by clinicians	Reusable speculum own by clinicians	Reusable speculum own by patients
• Cheaper • No time spent on sterilization • More polluting	• More ecologic • More expensive for hospital • Need time and a person dedicated to the sterilization • Need to buy extra speculum for sterilization time	• More ecologic • Pay by the patient and not the hospital • Less stressful because the patient knows the device • Women can inspect themselves by their own • Costly for patients

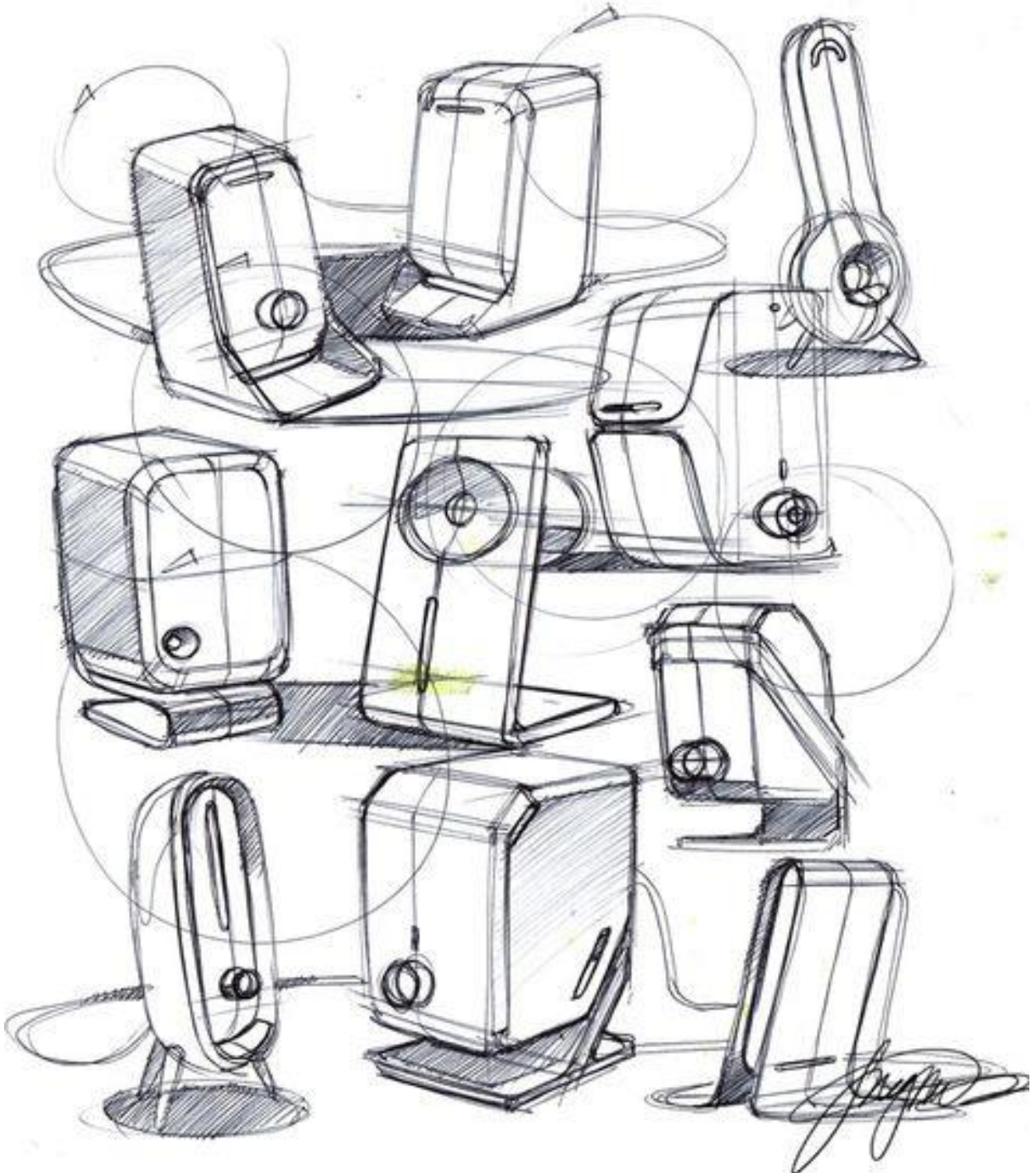
Reusable speculum own by patients

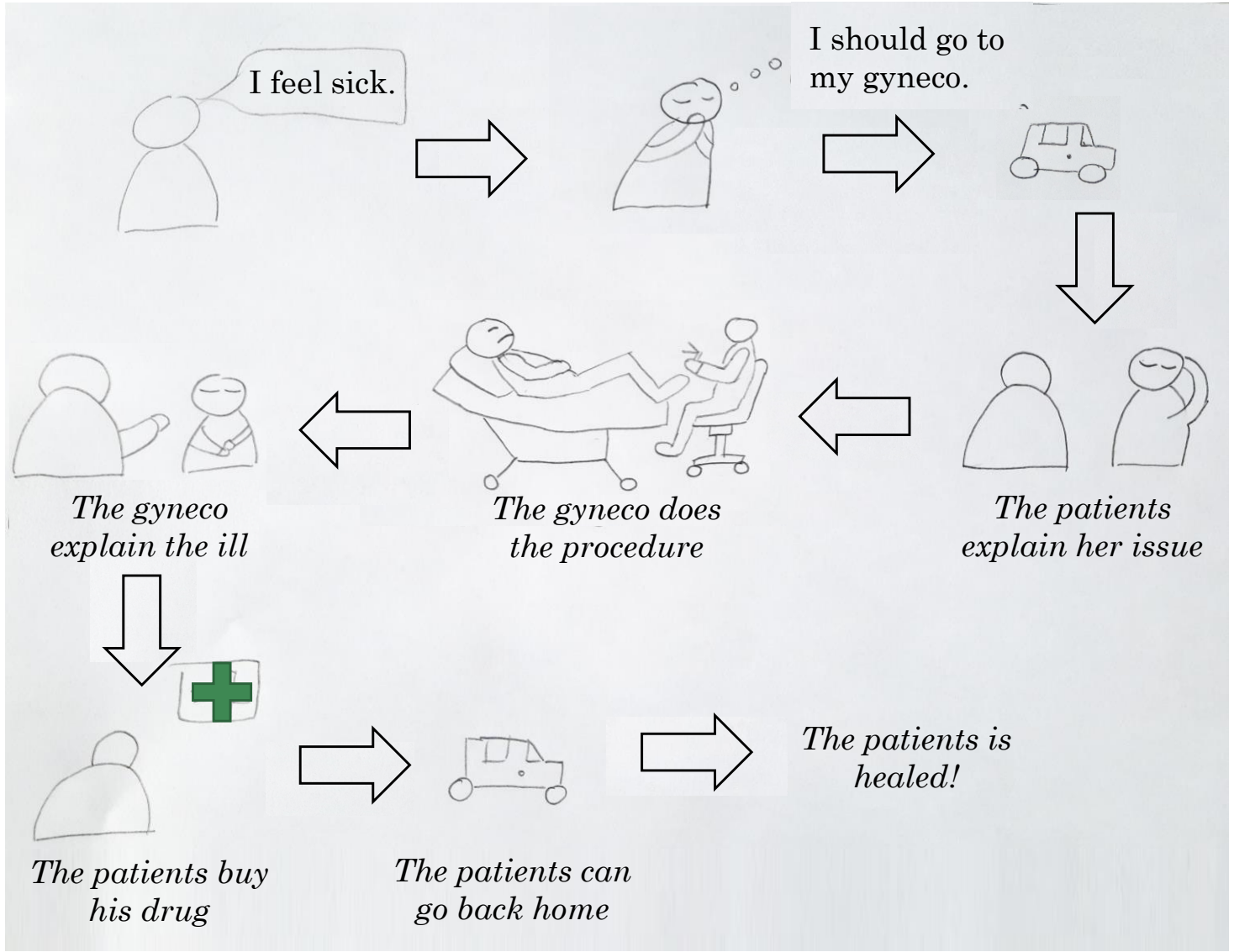
- With the above picture, the choice is obvious and unequivocal. However, this means that there will be more pressure on the side of the patients to buy the product. Why buy a product that is identical to the one the gynaecologist is already using? The answer is, it has to be drastically different.
- This is the only way that women will want to buy it and then have their gynaecologists use it on them for investigation or surgery.
- This adds another need, the device must allow women to perform simple inspections of their cervix.

Function	Definition	Criteria	Level	Flexibility
FC7	To enable patients to inspect themself	Visibility Usability	Clear vision of the cervix Doesn't occur pain or discomfort	F0 F0

Sketching

- This part is dedicated to all first draws.





Storyboard

- The storyboard represents the clinician's view. However, after analysis of my online questionnaire, many comments highlighted the lack of discussion between the patient and the gynaecologist.
- Most women complained about the lack of time and explanation given to them by their clinician, which added to the mistrust and stress of the speculum procedure.

Storyboard

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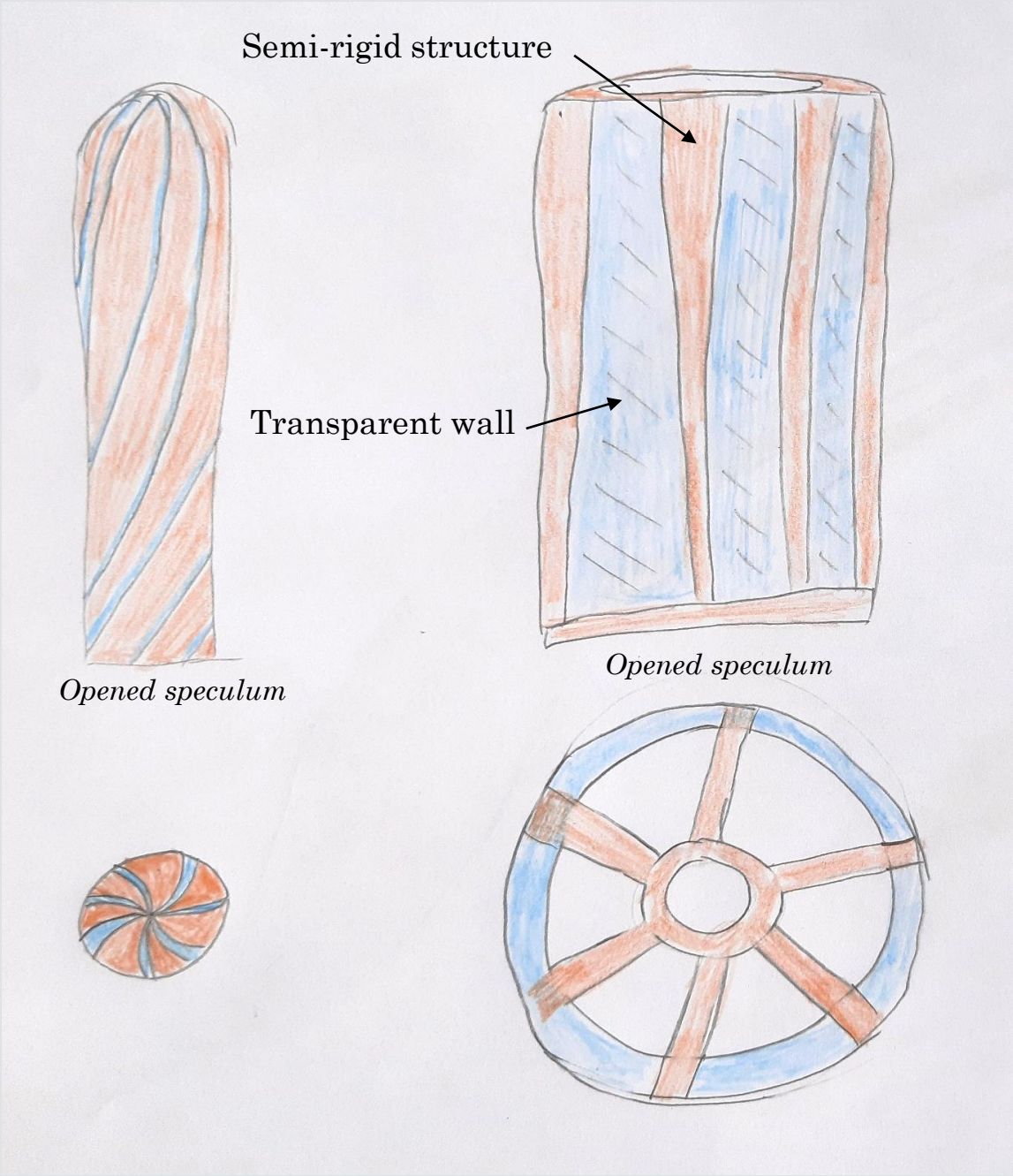
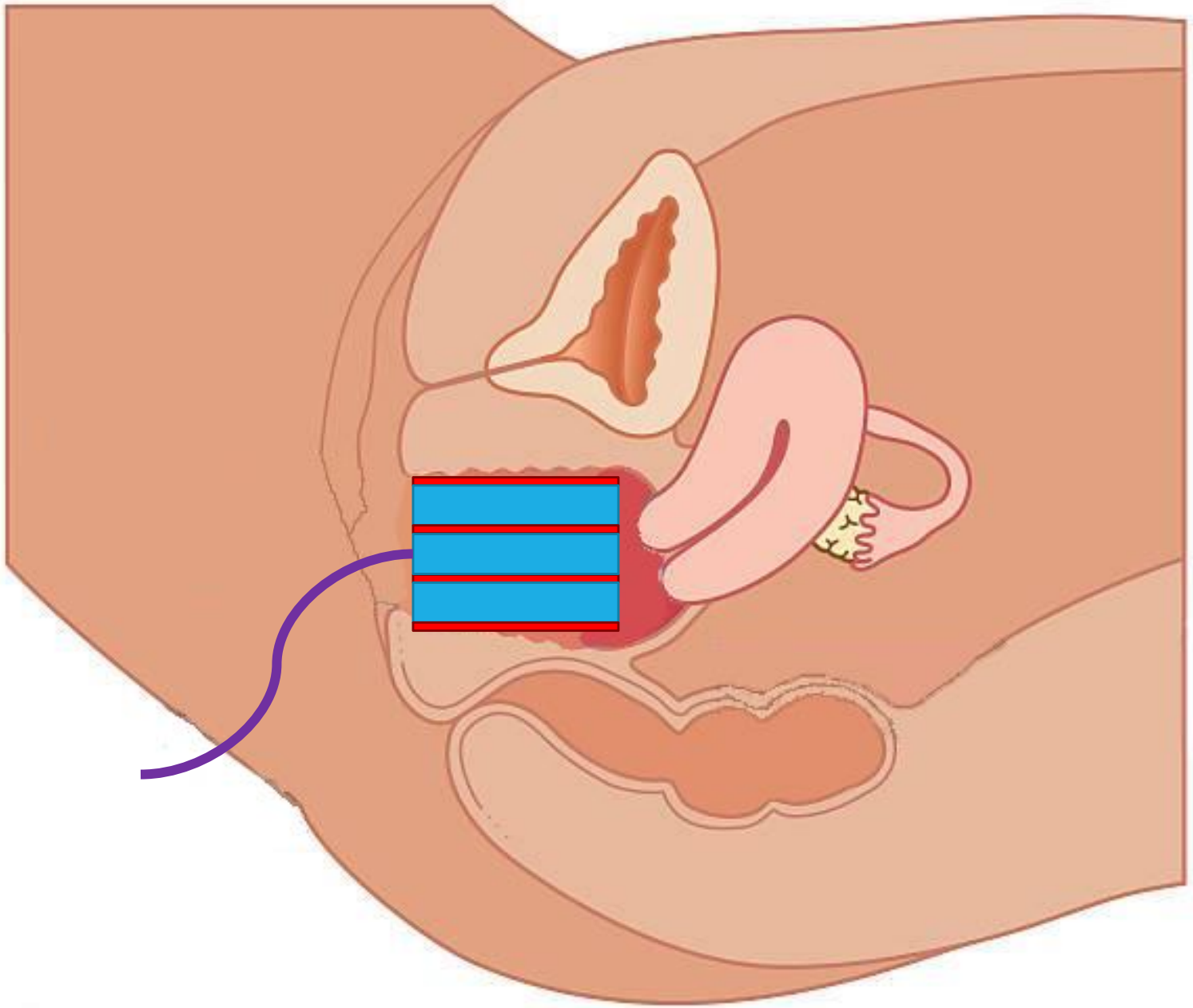


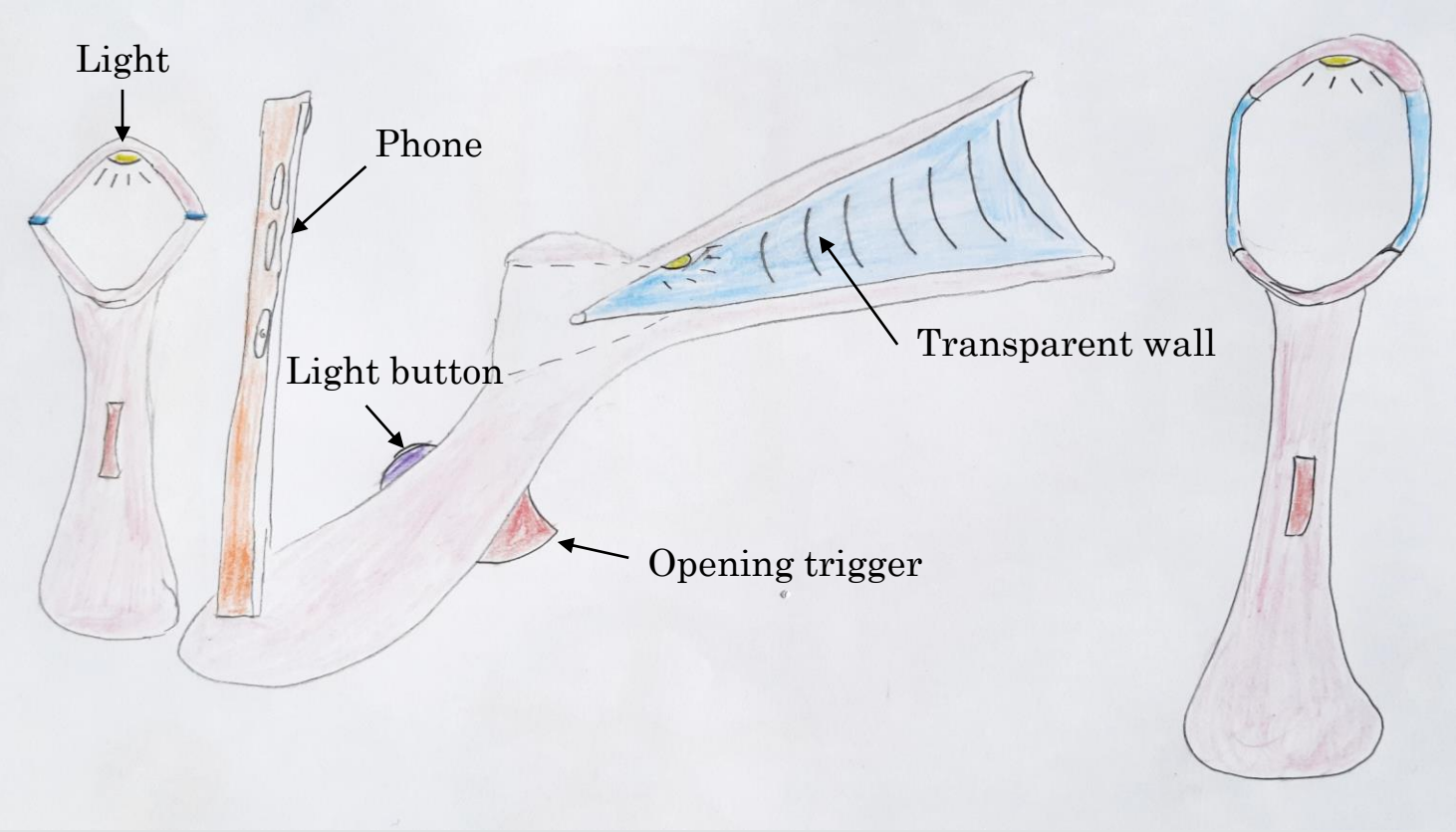
Tampon Design

- The principle of this design is simple, it takes the shape of a tampon when closed. The patient inserts it by herself, and twist the system allows it to take its wide shape.
- The gynaecologist can observe the walls of the vagina through the transparent plastic, as well as the cervix.



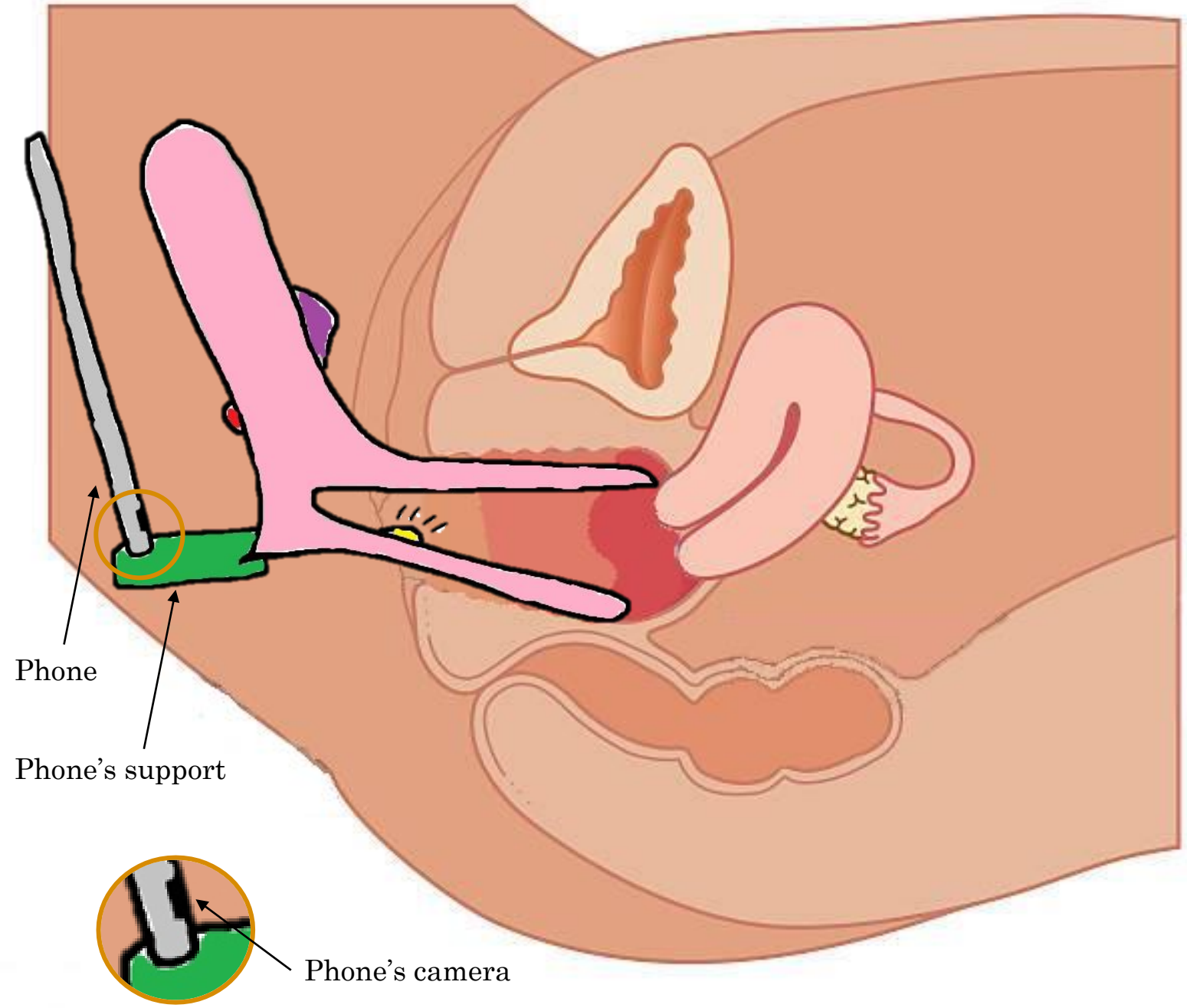
Tampon design

- This picture allows you to better observe the tampo in an open position in the vagina.
- I have added a wire to facilitate its removal so as not to disturb the patient.
- The disadvantage of such a system is that the clinician has no control over the system once it is open. He only has a closed and open position.



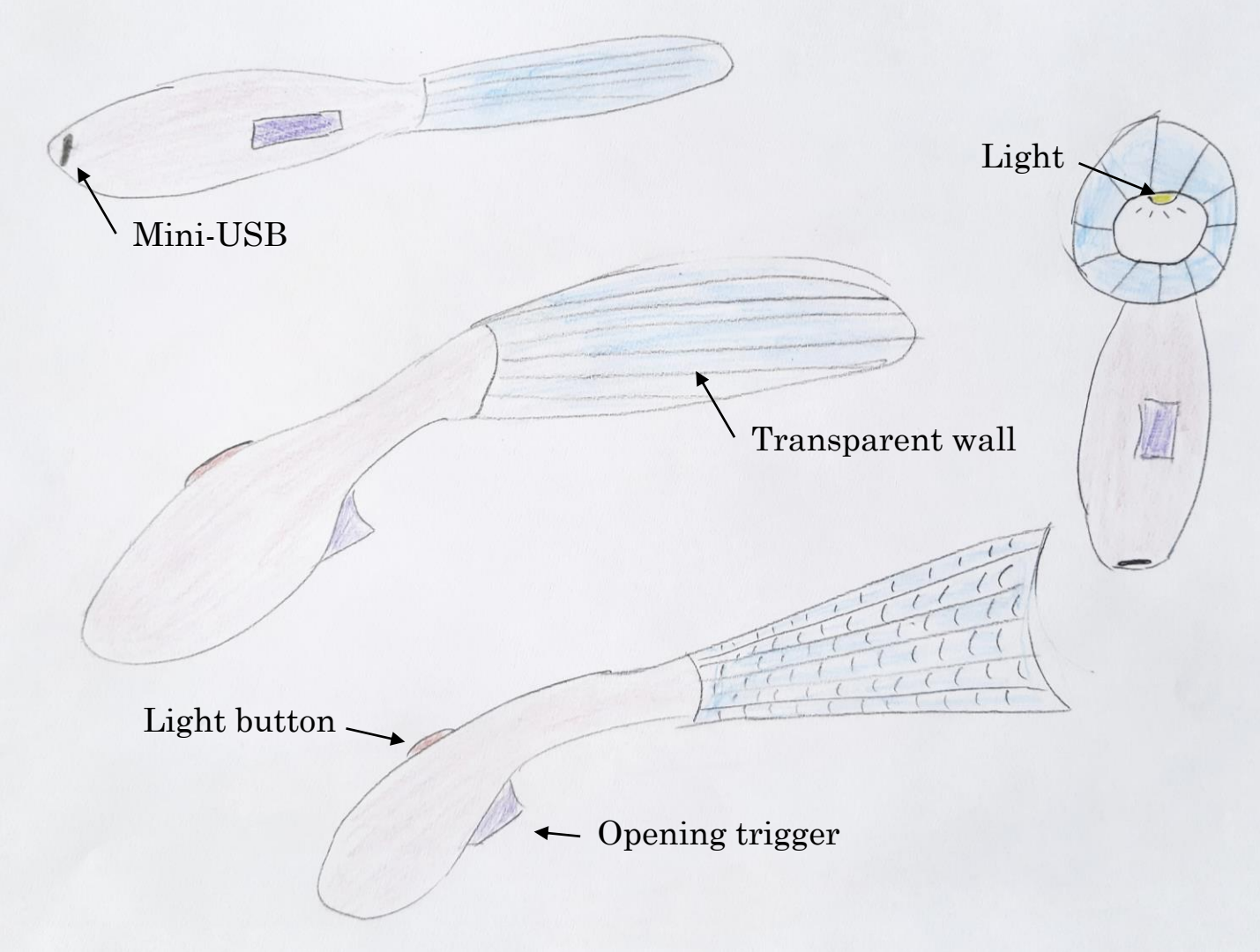
Self-use design

- The principle behind the design is to produce a product that can be used by a clinician as well as a single woman.
- For women, it is a way for them to get to know their bodies better and to raise awareness of the health problems that surround them, particularly uterine cancer.
- The possibility of carrying out their own smear test is also being considered as this is one of the requests that has been raised through the online questionnaire.



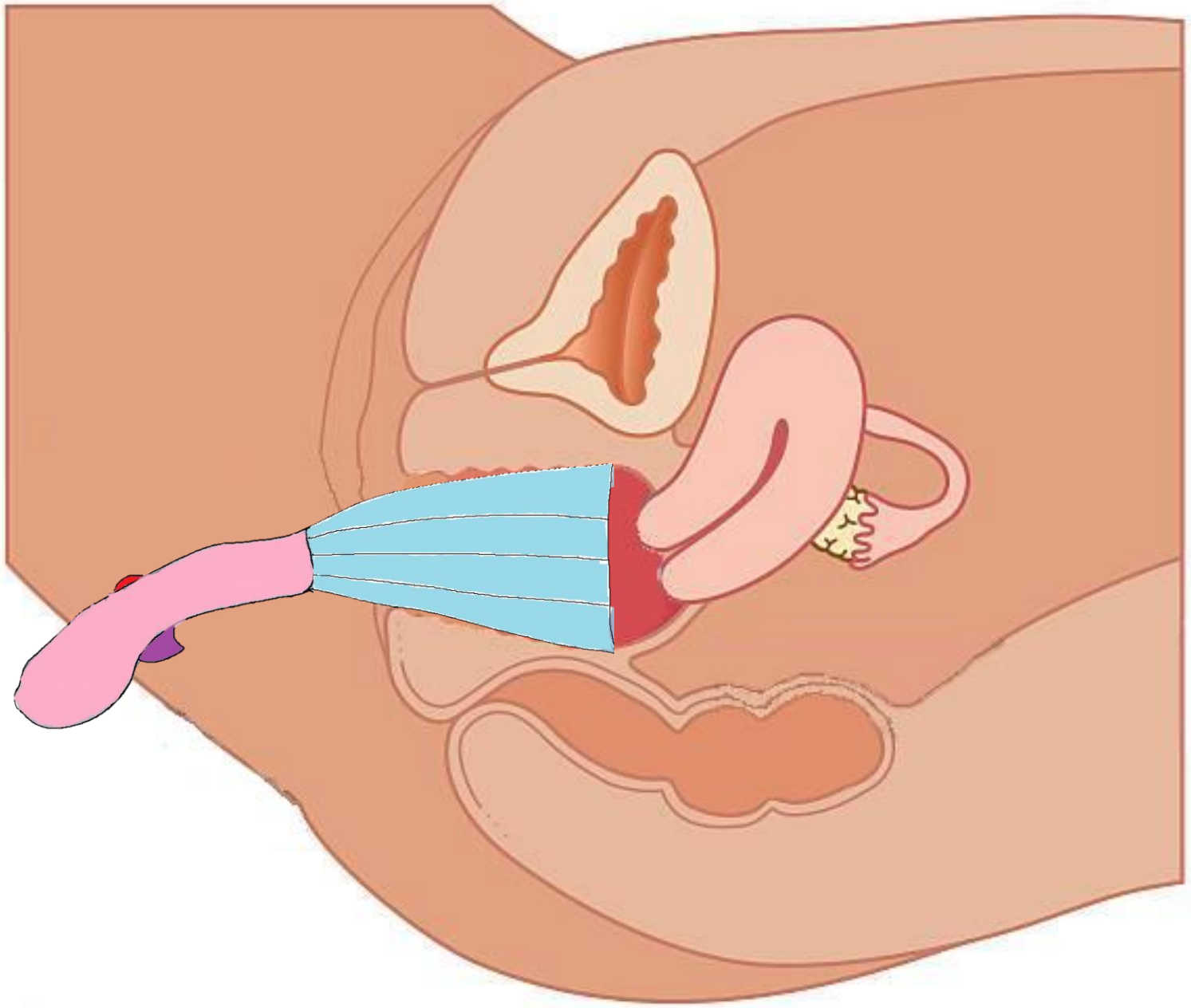
Self-use design

- The diagram shows the basic speculum and the addition of a green stand to hold the phone in a vertical position.
- Thus, it can be used as a mirror or a camera.
- It should be noted that this solution can be added to that of the transparent wall or the additional slats if one simply develops a clip-on support for example.



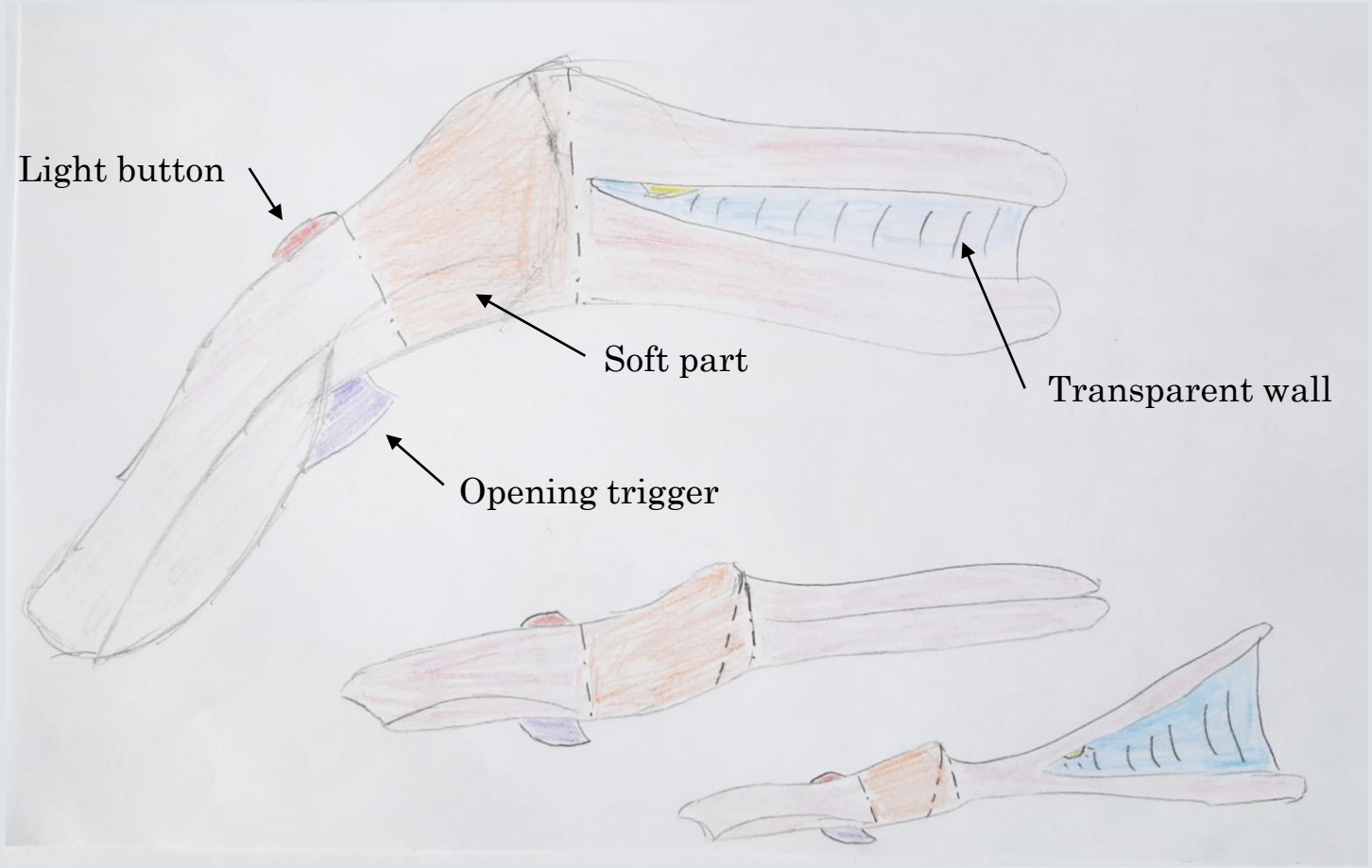
Umbrella design

- As the name suggests, this design opens in the same way as an umbrella. Except that the fabric walls are made of clear plastic to allow maximum visibility for the doctor to observe the vaginal walls.
- I have also added a mini-USB port to charge the system which runs on a built-in battery.



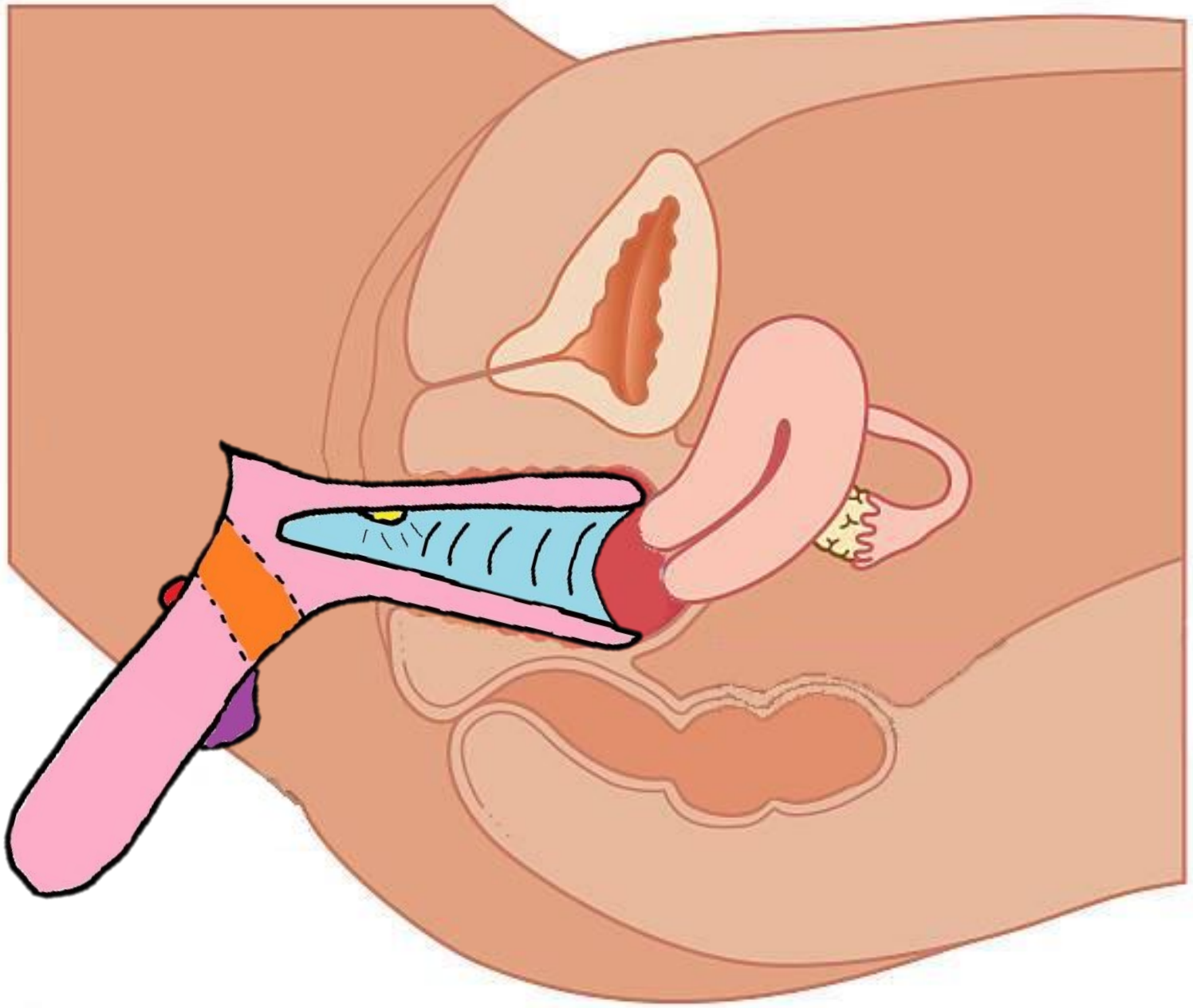
Umbrella design

- In the image, the use of this design can be better seen. It is clear that the shape is more complex than a simple cone to allow the clinician to block the walls without creating discomfort for the patient.
- In addition, the rods used should be sufficiently rigid to withstand the closing force of the vagina.



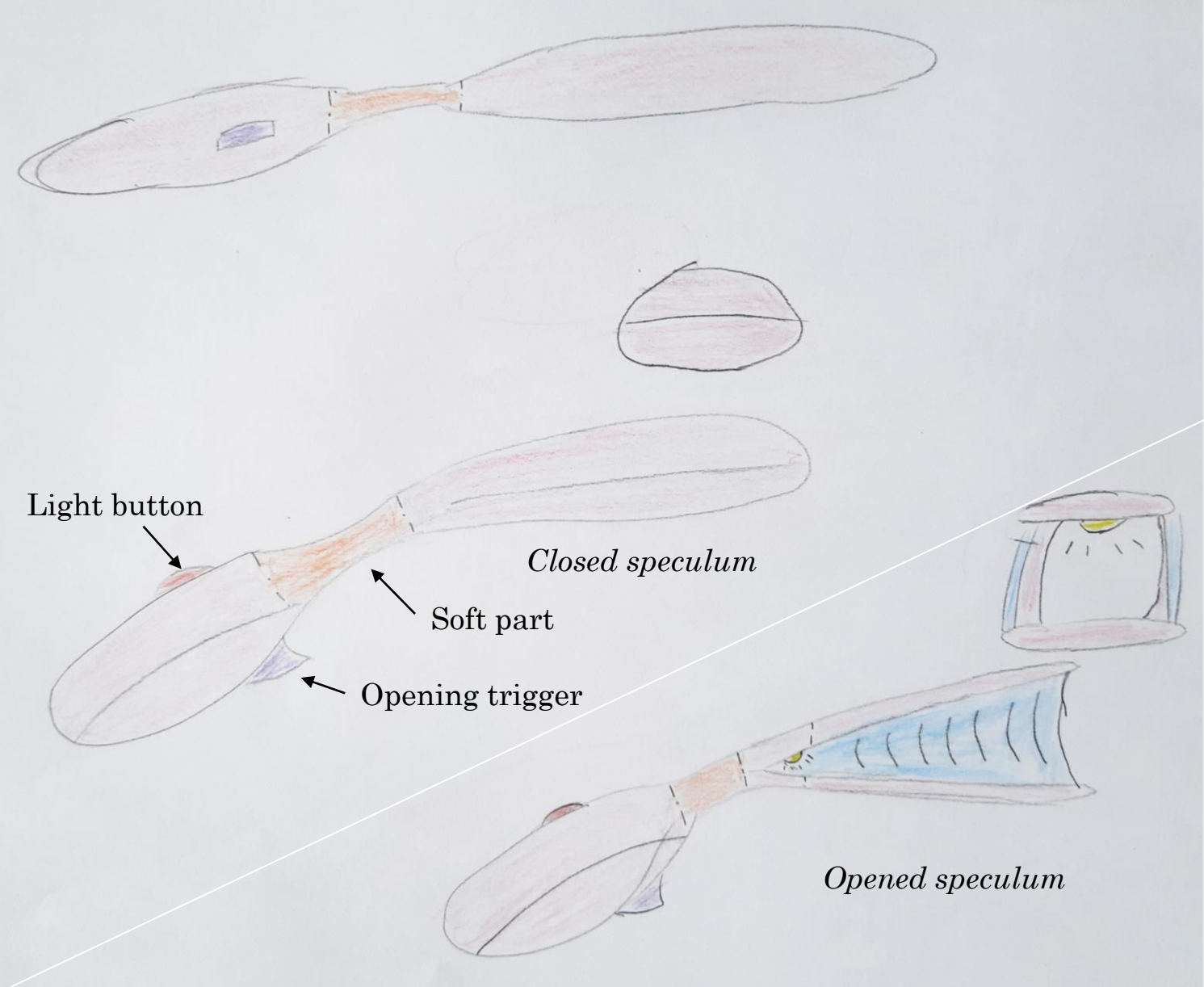
Flexible design 1

- The idea behind this design is to produce a product that can be twisted so that it can be easily used by a clinician or a single woman.
- Thus, the part between the spout and the buttons can be twisted up to 45° thanks to the use of a softer plastic.



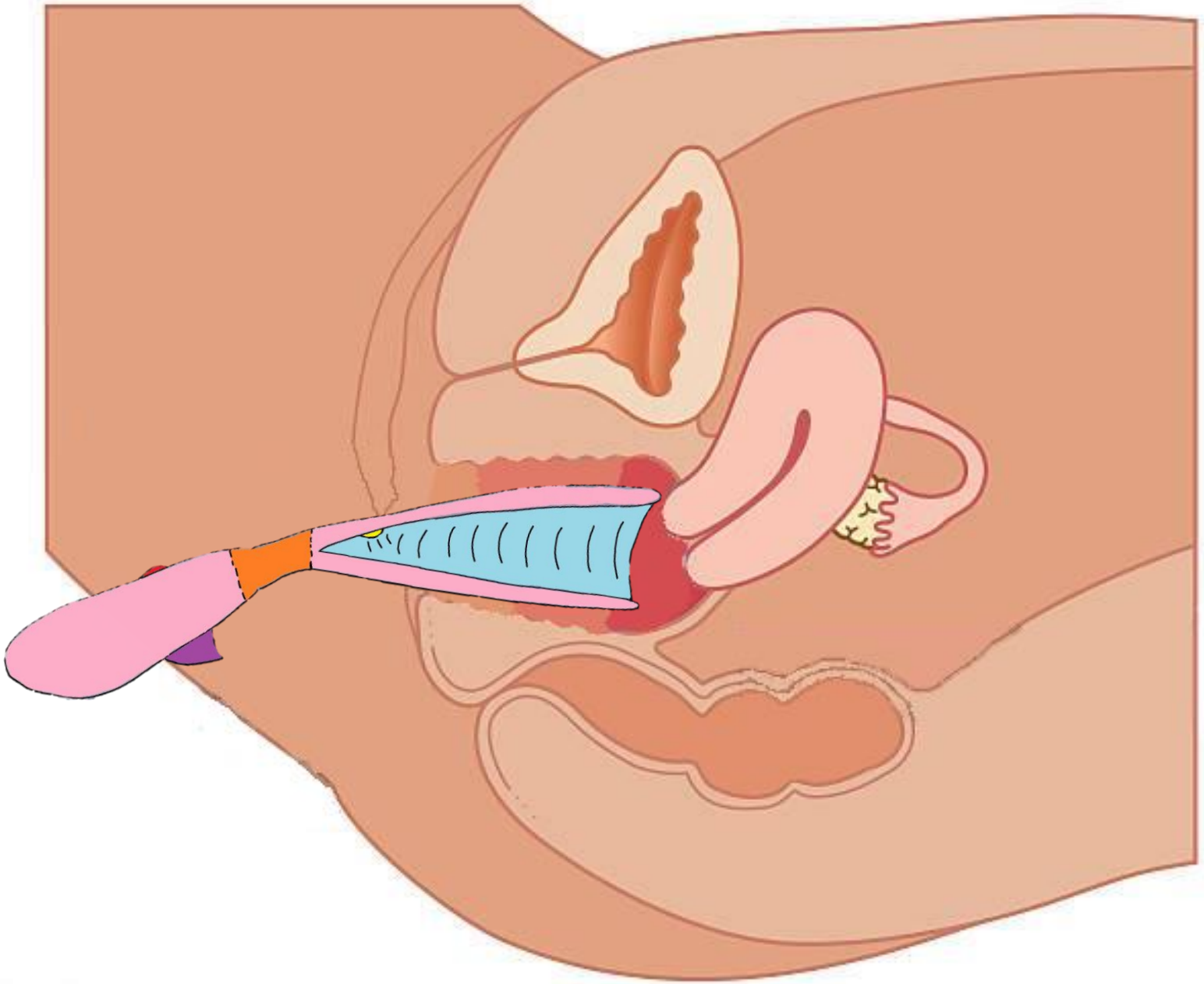
Flexible design 1

- The most important thing about this design is that the added complexity of manufacturing due to the difference in plastic material used in the handle must be balanced by the gain in ergonomics for the user. Which I doubt, unfortunately.



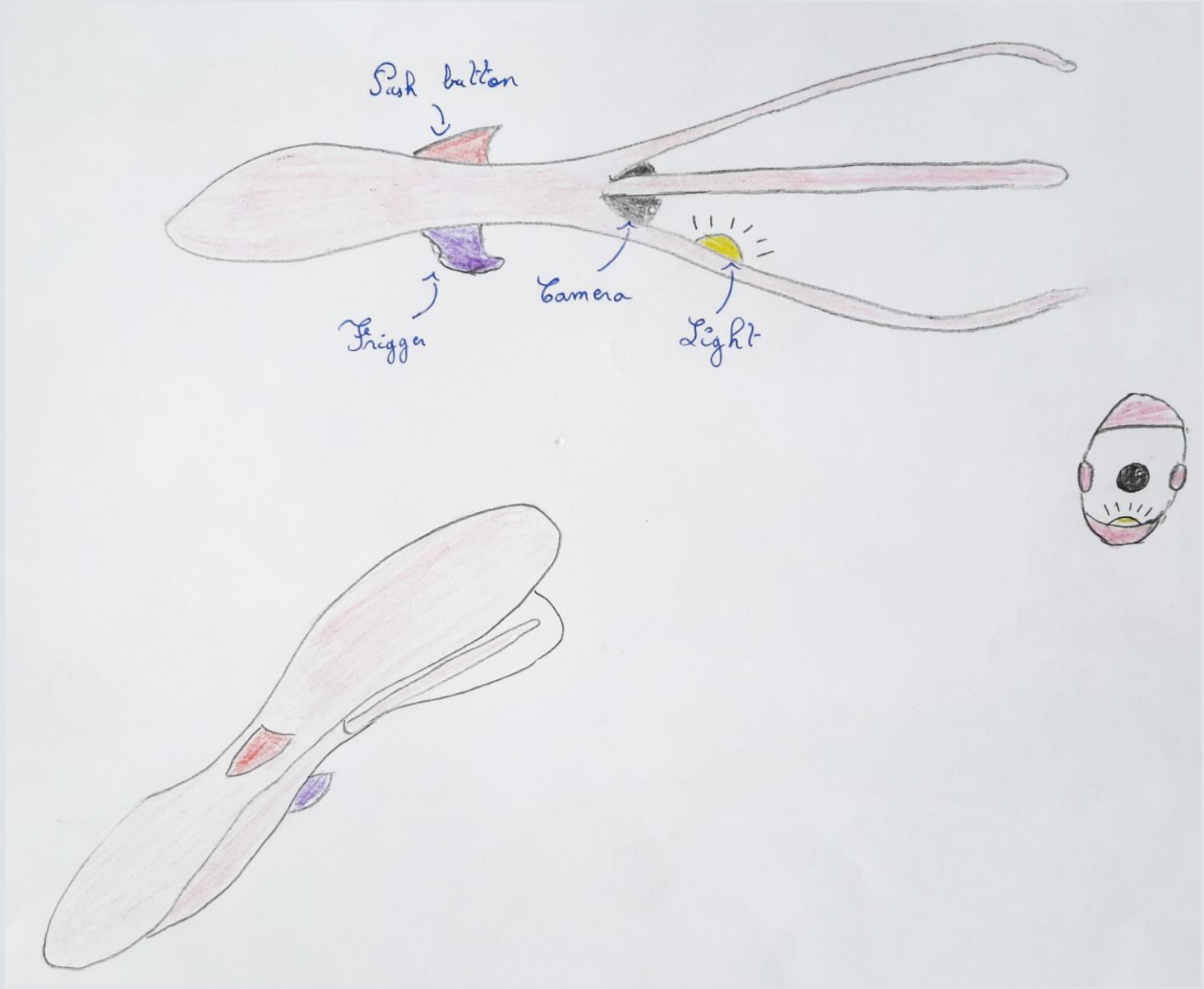
Flexible design 2

- Here, the concept remains the same, only the handle and the shape of the beak change from the previous design.
- My goal is to find the best shape to eliminate the pain and the maximum of discomfort during the procedure.



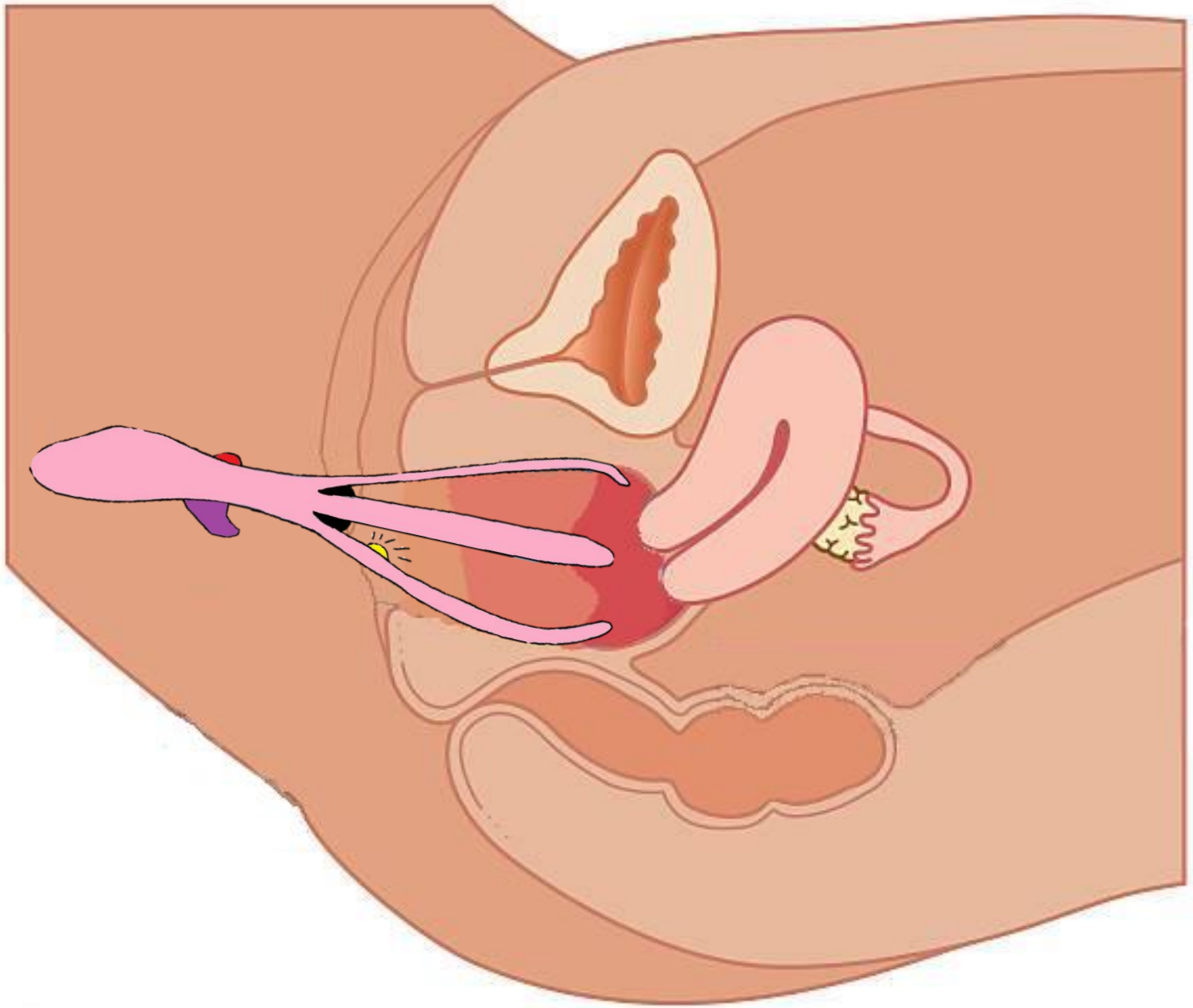
Flexible design 2

- The concept similar to the first one will have to go through a prototype phase to find the most perfect shape for the clinician during his observation and for the patient's comfort.



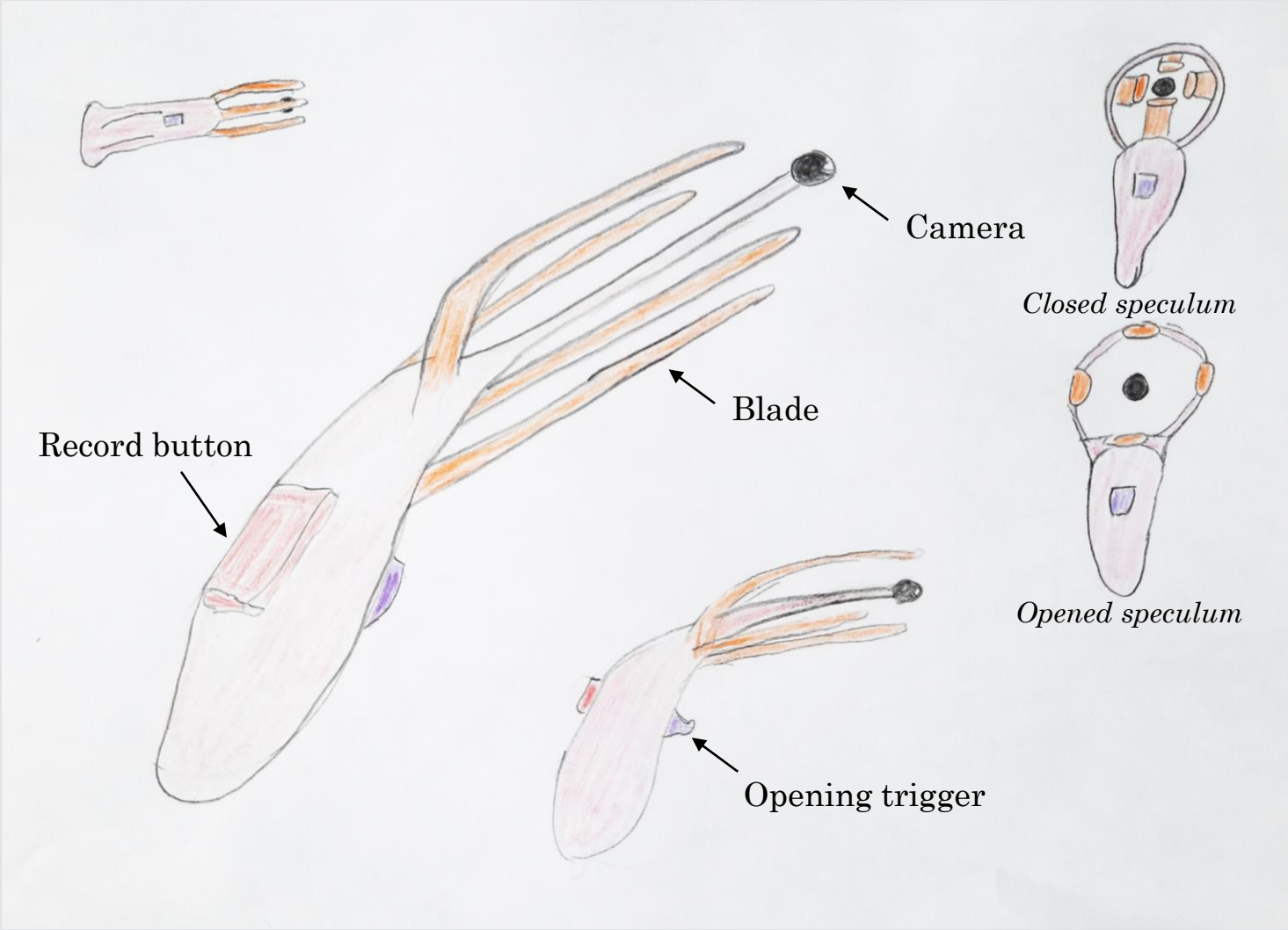
4 Blades design 1

- This design includes two new technical solutions that I considered: a camera and two articulated arms.
- The idea here was to see if the idea of transparent walls was really relevant and if it was not possible to use a camera instead of the clinician's eyes.



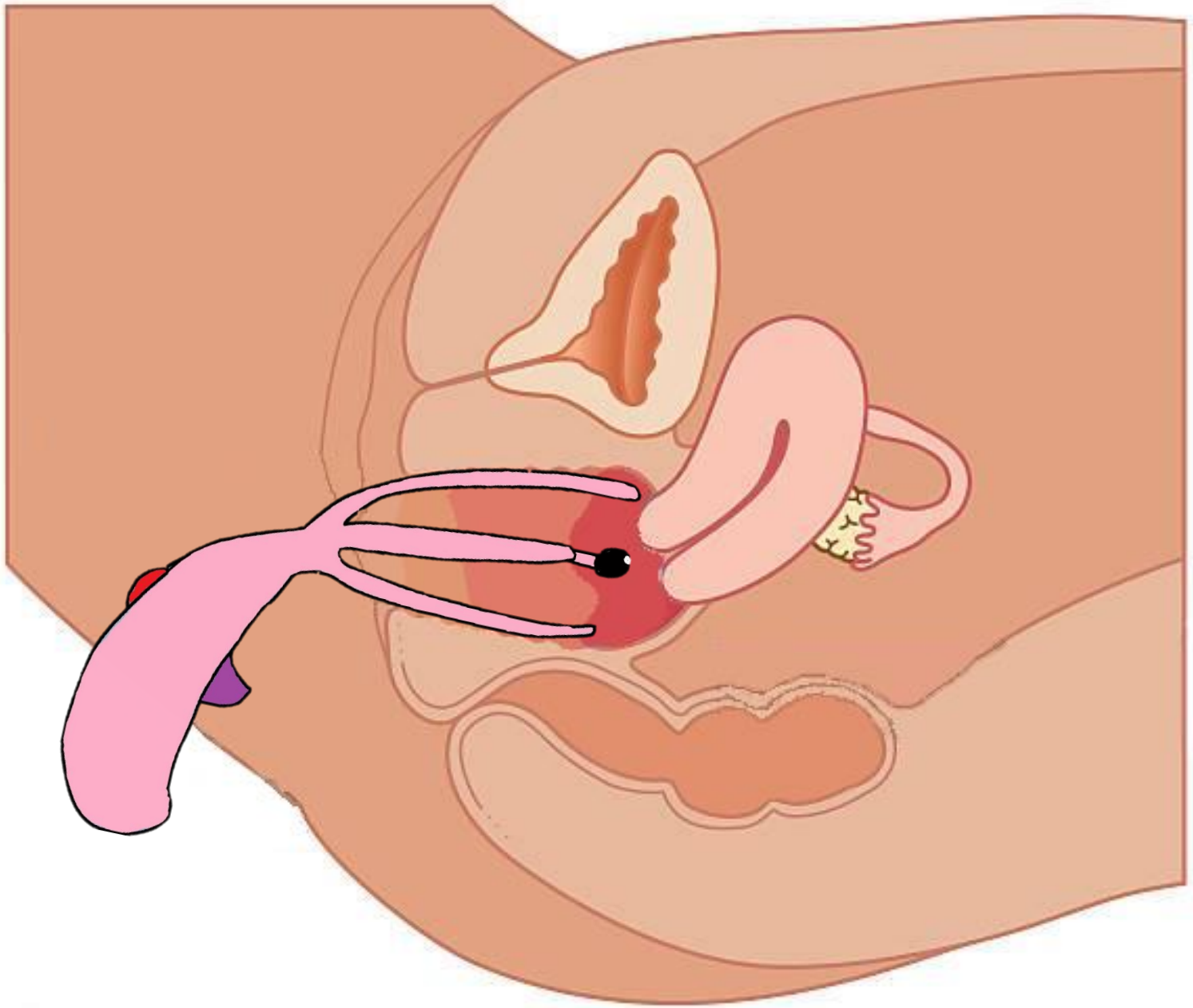
4 Blades design 1

- The clinician's use of the product with the addition of the camera could add comfort for patients as they would no longer have to look directly at their vagina, but simply a computer screen that would relay the images taken by the speculum, much like a ureteroscopy.



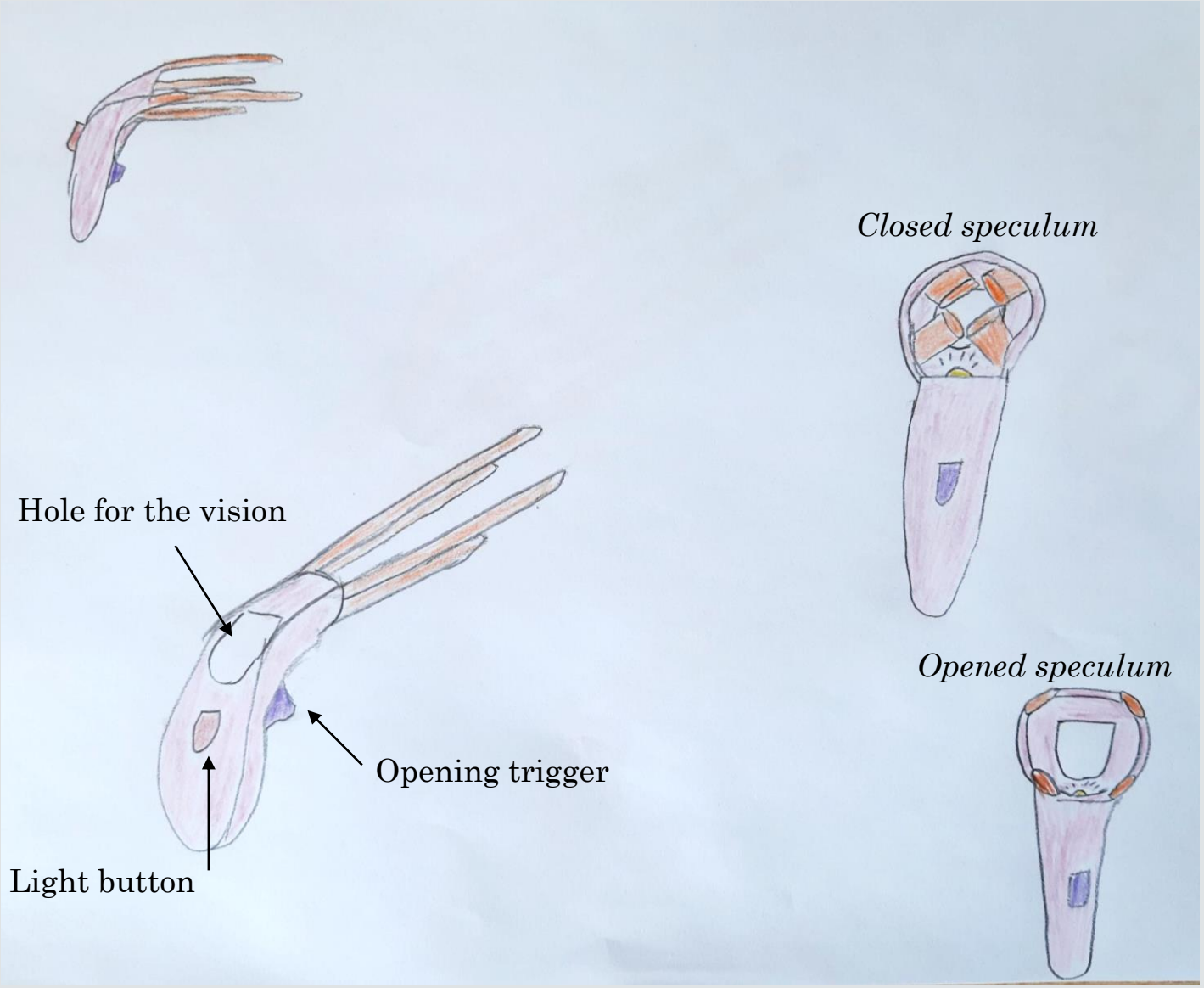
4 Blades design 2

- Once again, I decided to create a design with a camera. However, it should be kept in mind that such a solution would not allow to perform procedures other than those limited to observation.
- It is therefore an expensive technology that reduces the functionality of the product.
- Videos and pictures would be recorded via a Bluetooth system and could be watched on a computer or a smartphone.



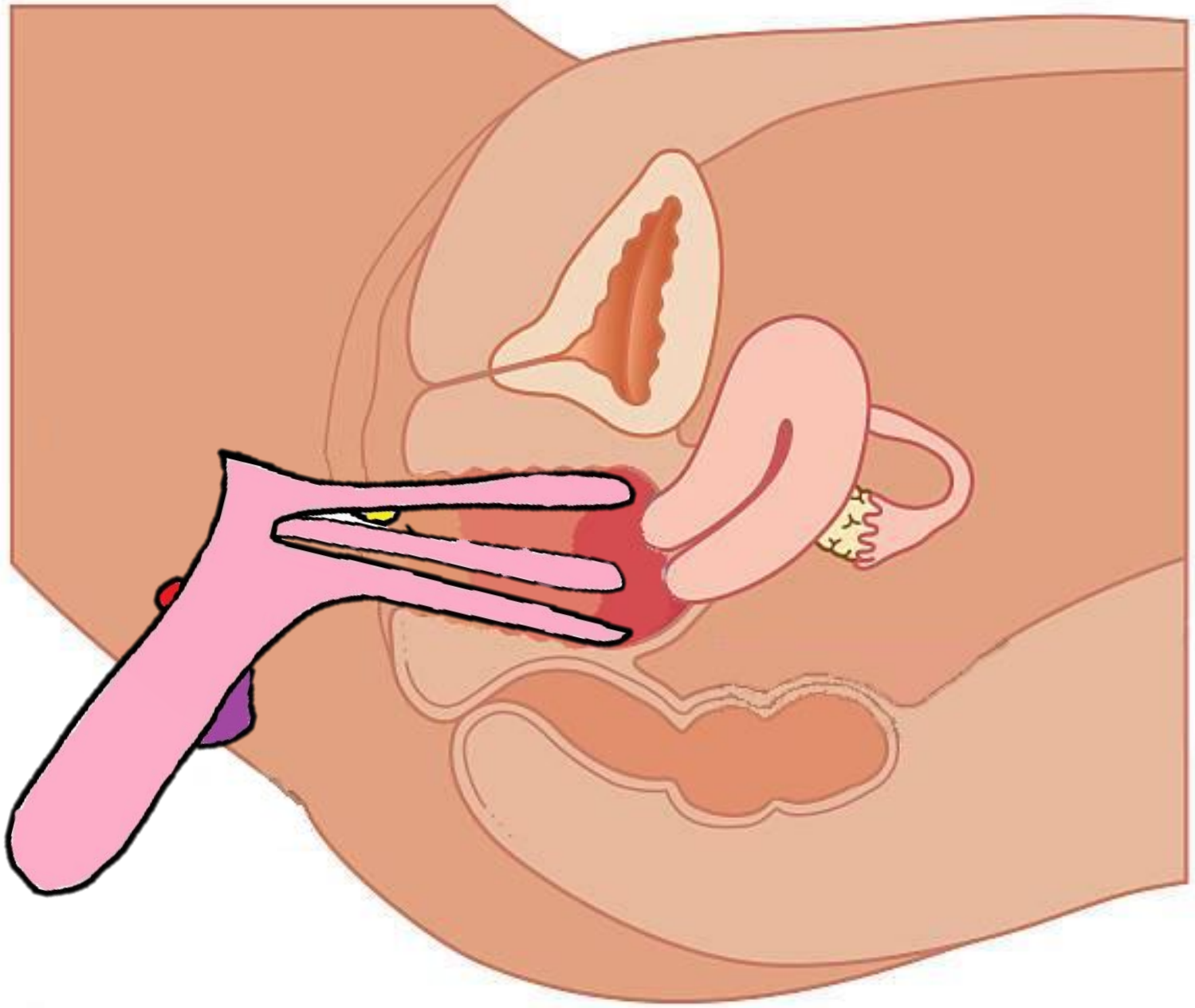
4 Blades design 2

- This second design simply sees the camera change position while keeping the handle close to the existing one.



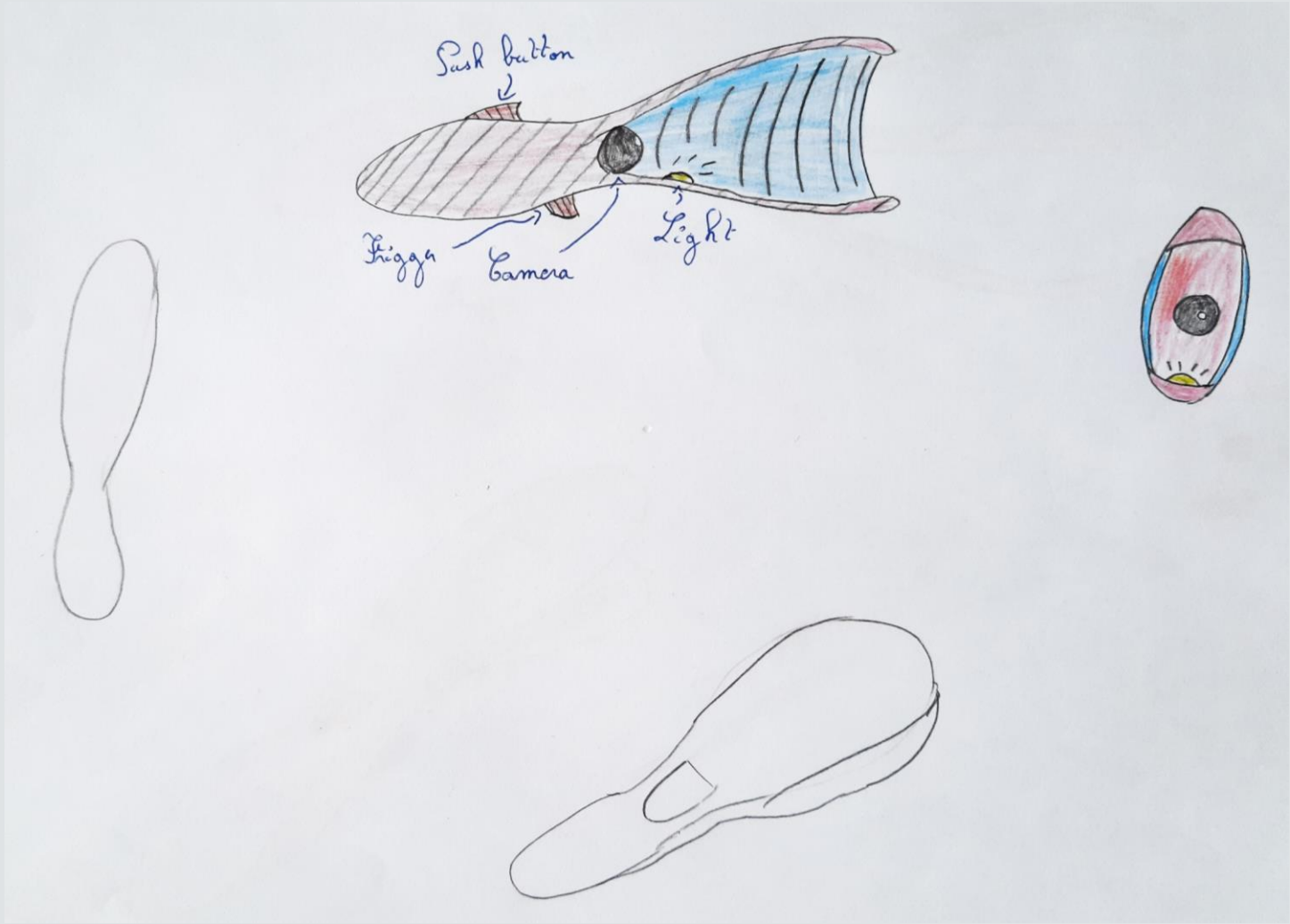
4 Blades design 3

- This time, I decided to part with the camera due to cost and product limitation issues.
- I also decided to rotate the blades of the speculum to get a different view of the product.



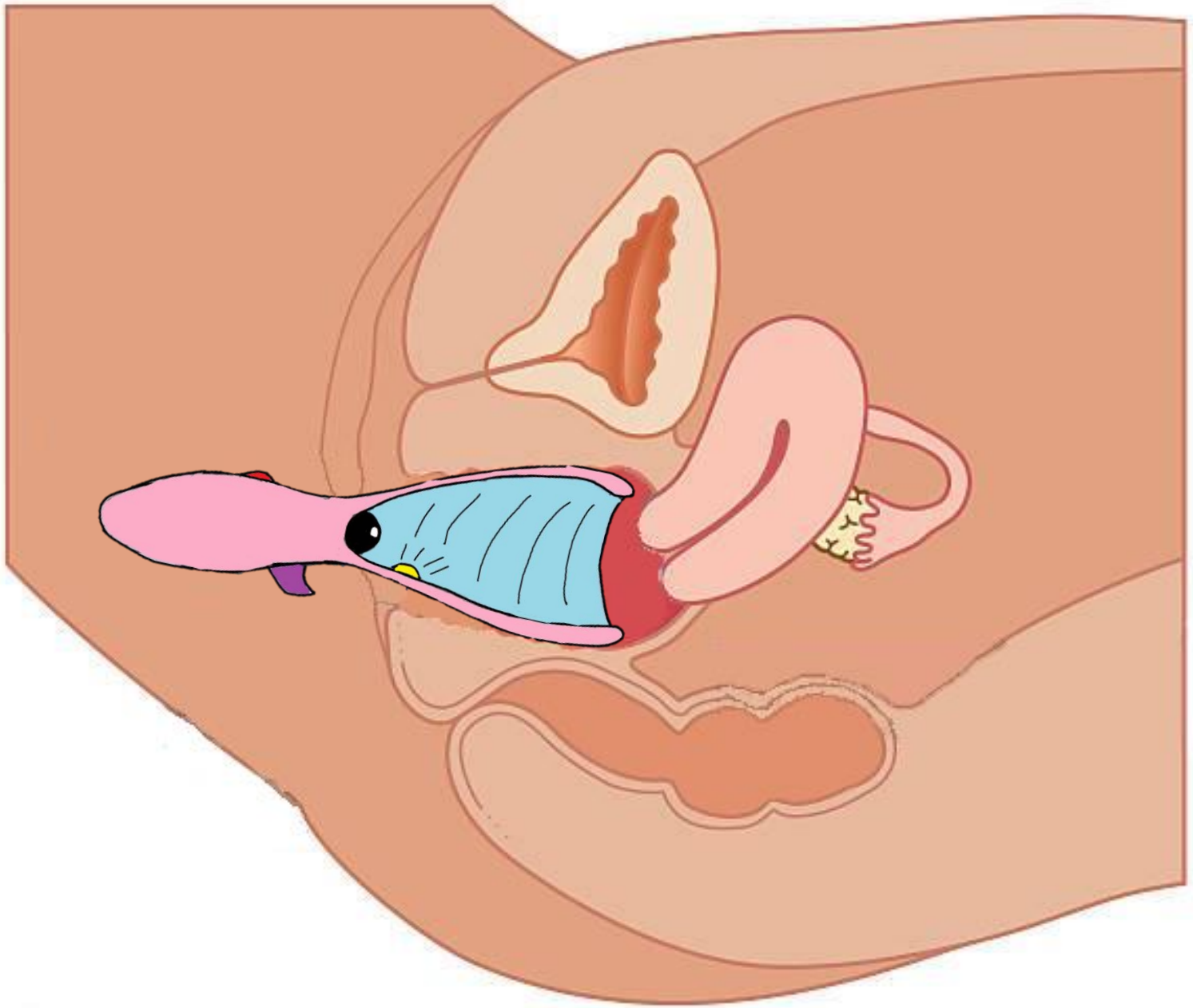
4 Blades design 3

- This design is similar to the one proposed by the Nella-NuSpec. The only difference is that I think the blades should be wider to provide more rigidity and I would like to see the shape of the speculum beak evolve completely to provide more comfort for patients.



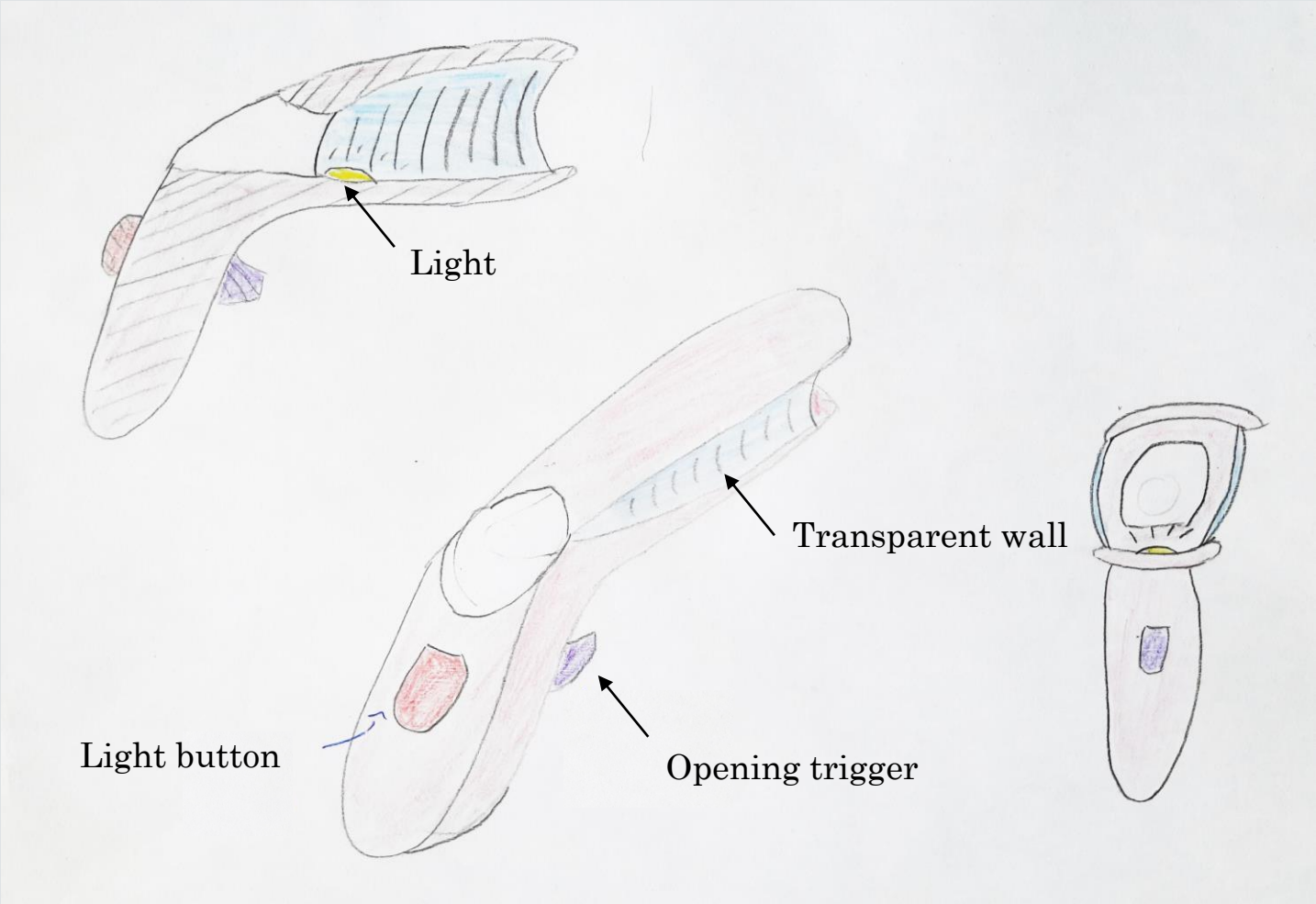
Wall design 1

- This design, which looks close to a cuttlefish, is again based on a solution that integrates a camera inside the product, serving as an eye.
- Again, the idea is to use a camera to reduce the stress of the device and allow the patient to use it alone at home.



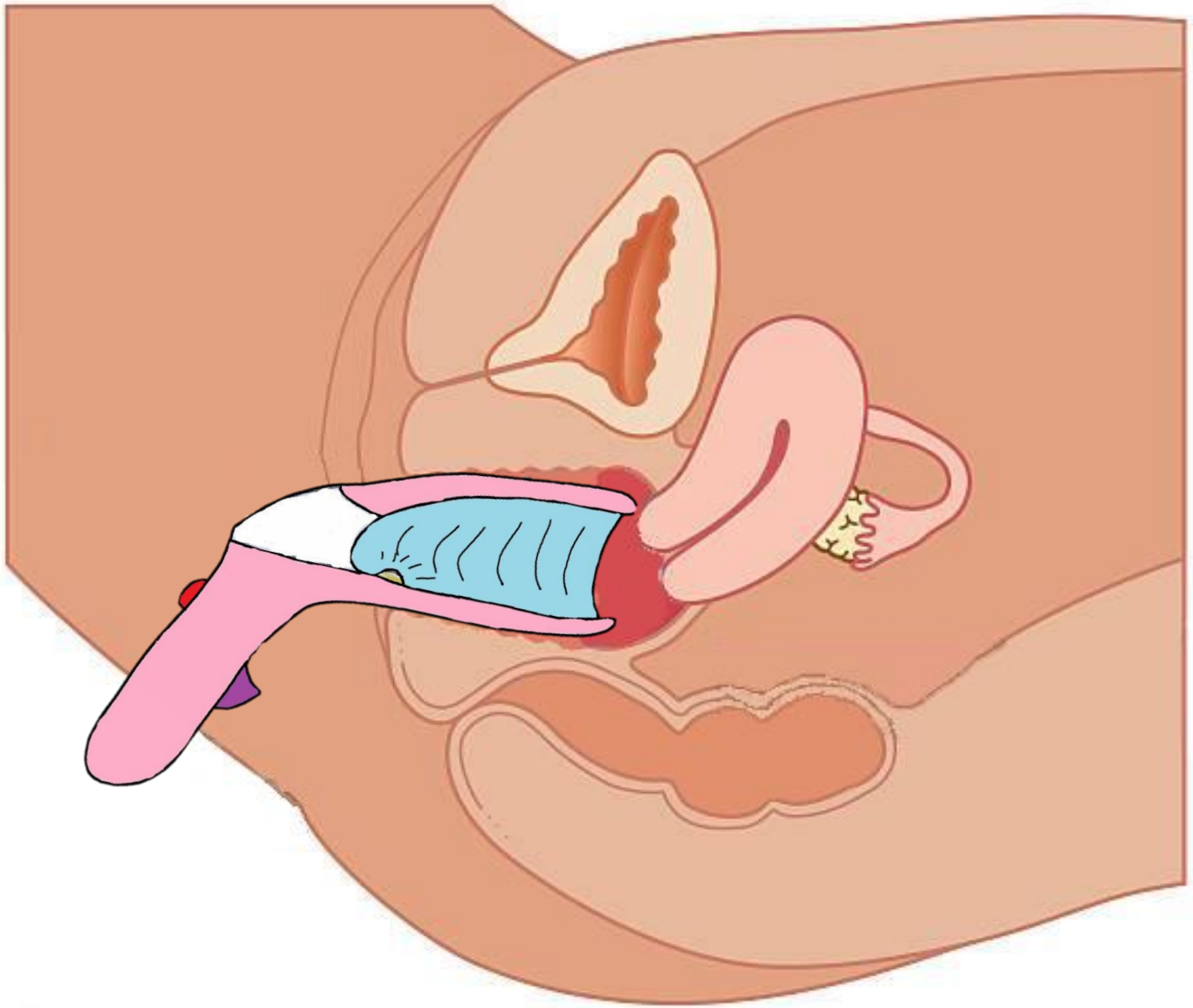
Wall design 1

- This rather ordinary looking design has the same qualities as the design blade oven, except that it has two transparent plastic walls that are supposed to prevent the walls of the vagina from obstructing the view.



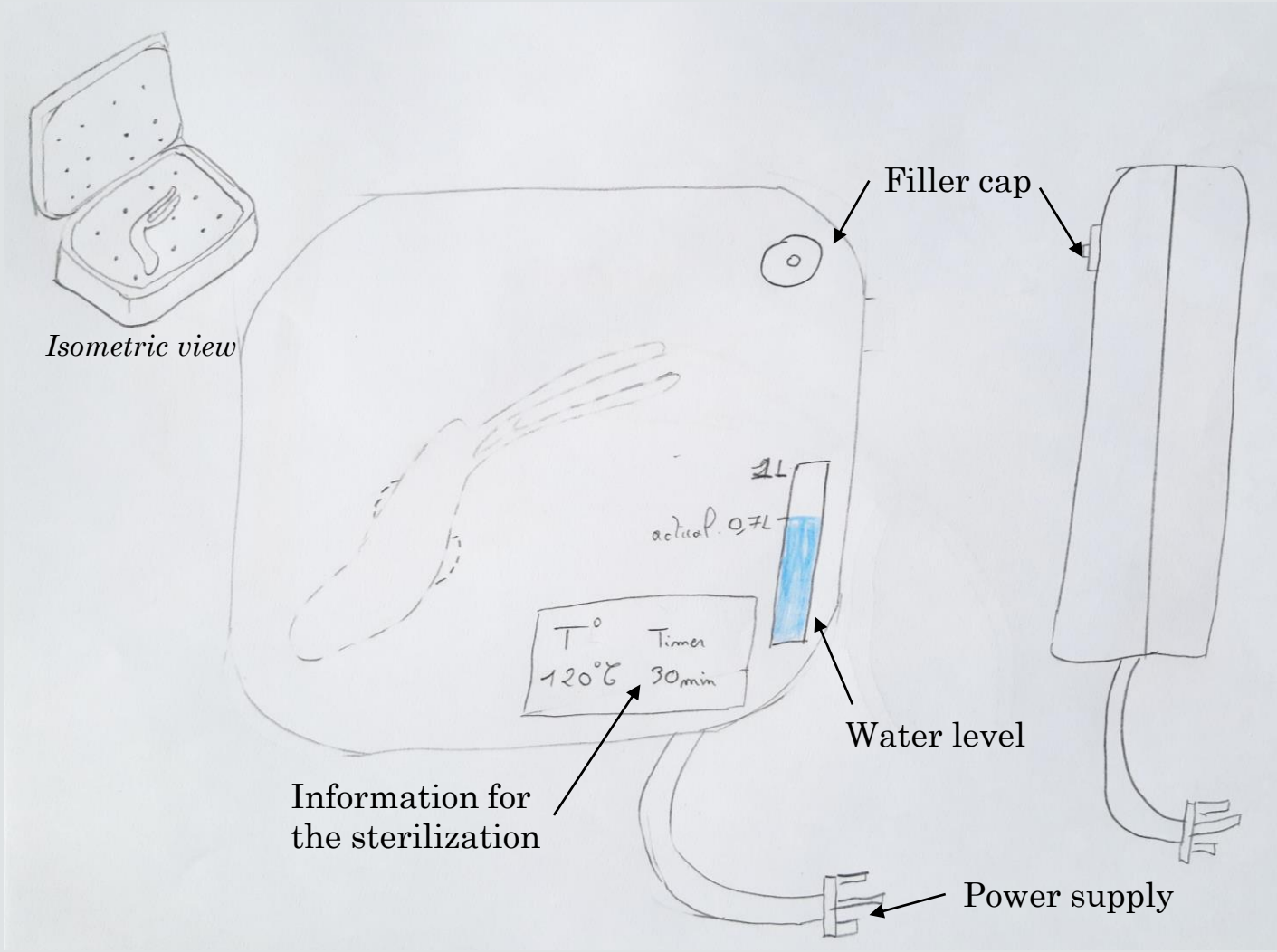
Wall design 2

- This new version of the speculum with transparent walls has an additional difference in its design.
- The open position is the basic position of the product, the trigger must be engaged to close the product.
- I thought that a mechanism like this could perhaps give the clinician more strength to fight against the closing of the vaginal walls.



Wall design 2

- This design is currently the one I think is the most promising. It allows me to meet all my clients' needs.
- I just need to make sure that I choose the right material for the transparent walls to provide optimum visibility of the walls and comfort for the patients.

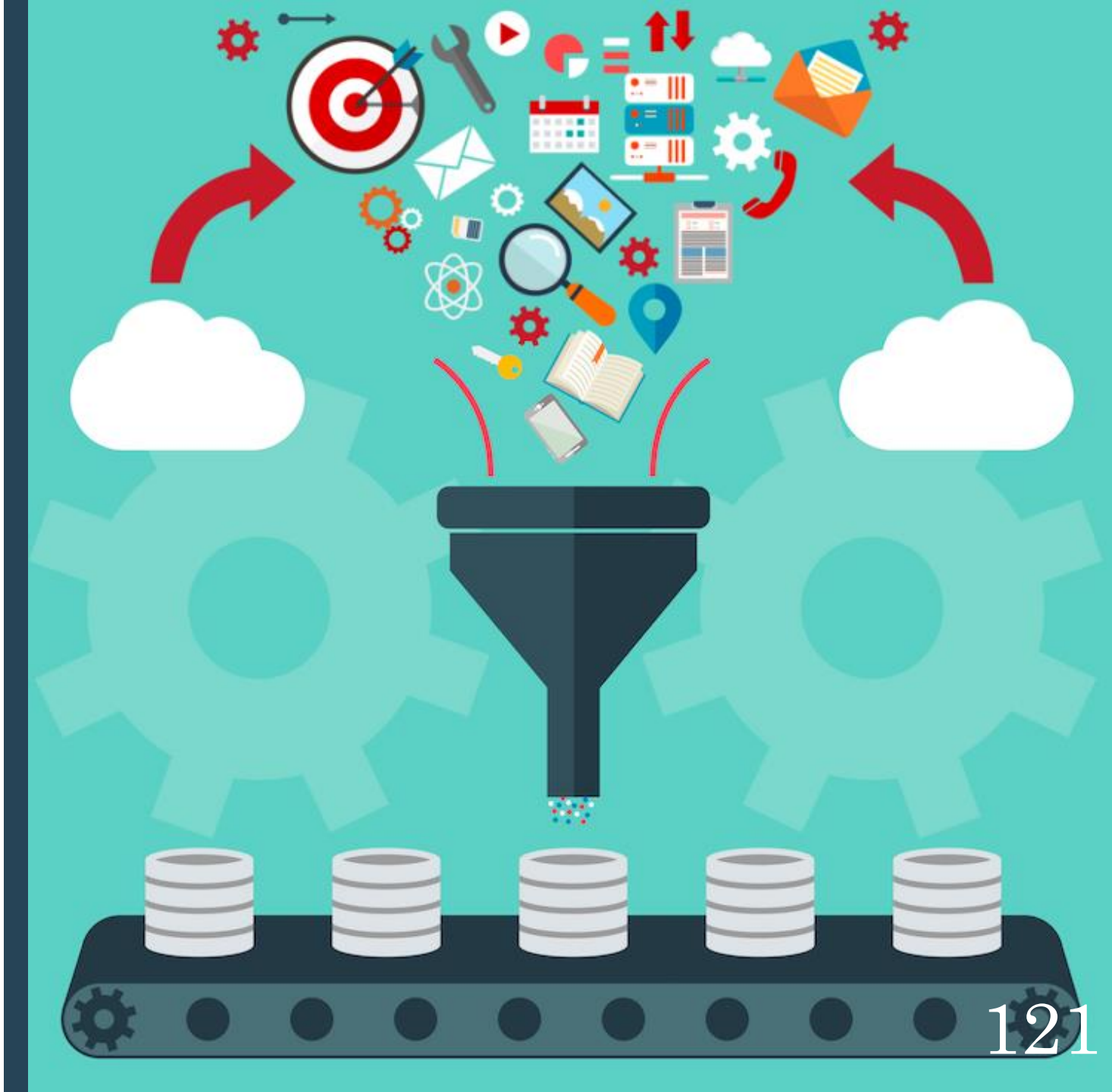


Sterilization box

- The idea behind this box is to offer an easy-to-use tool to sterilise your speculum.
- Clinicians and patients alike would simply place the speculum in the impression, fill the system with water and then plug it into the mains to sterilise the product under pressure in about 30 minutes.

Filtering

- This part is dedicated to choose the main idea that I want to lead to the end of the process.



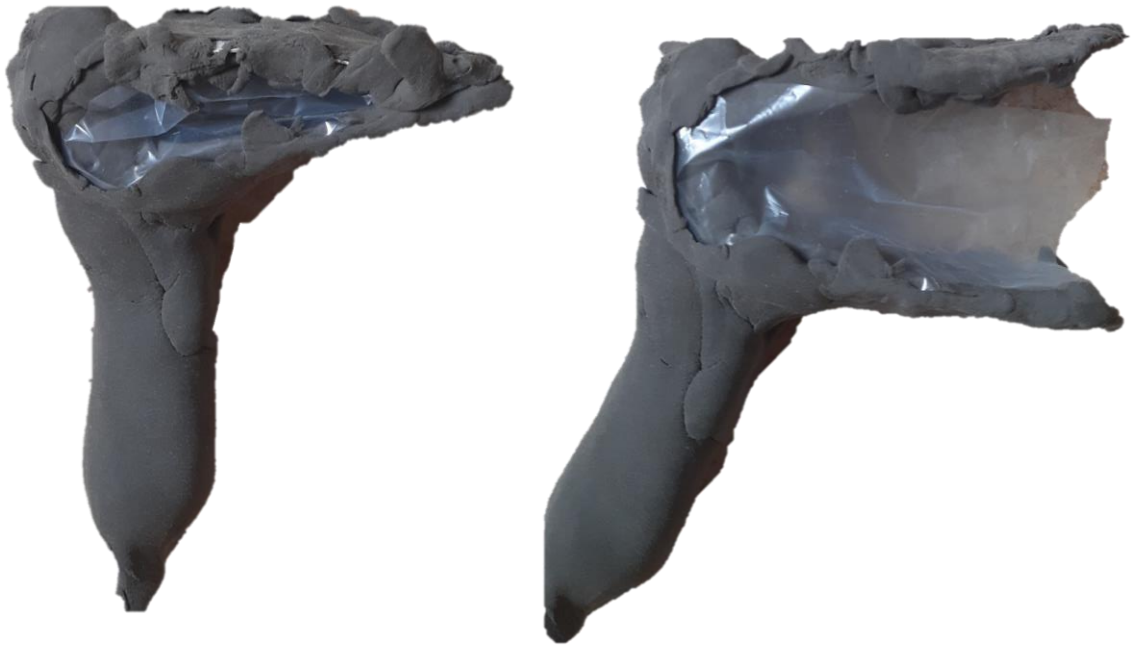
3 Main concepts

- Here, I focus more specifically on the technical solutions. The choice of the shape of the speculum's mouthpiece will come later. I intend to produce a large number of designs once the choice has been made, as this will allow me to avoid creating ideas that would not allow me to use the technologies that I have validated, such as adding a camera, additional blades, transparent walls, etc.

Prototype structure

- In order to be able to choose the best technical solution, I decided to quickly produce prototypes using modelling clay.
- The idea behind this is to be able to easily modify my design while testing it in my hands. This choice of solution allows me to save a lot of time compared to 3D printing because I don't have to go through the 3D design phase via Solidworks.
- However, this technique does not only have advantages. Indeed, the modelling clay is soft and hardens slowly in contact with air. I therefore inserted pieces of cardboard to serve as a framework for the structure.

Transparent wall prototype



- The first prototype I produced is far from perfect, but it allowed me to see the complexity of the product, as well as its use.
- Here, the aim was not to find the final shape of my speculum but simply to allow me to identify the qualities and defects of this technical solution.
- I realised that I would have to choose between sterilisable or disposable walls. But in any case, the walls had to be easily interchangeable because if I choose the sterilizable walls and one of the walls is damaged, the user must be able to easily change it.

Transparent wall prototype

- In addition, transparent walls should not reduce the visibility of the clinician. This is the number one priority when considering the choice of sterilizable or single use.
- The choice of material should also take into account that its contact with the vagina should not be an additional discomfort for the patient.

Self-use prototype

- For the second prototype, I set out to understand how a woman alone in her home could easily use the speculum to observe her cervix or do a smear test.
- So I first tried it in a standing position with a mirror on the floor. I immediately realised that this was the worst solution as it did not allow a good view and was not comfortable.
- I then tried it on a chair and I saw that the position was not practical either..

Self-use prototype

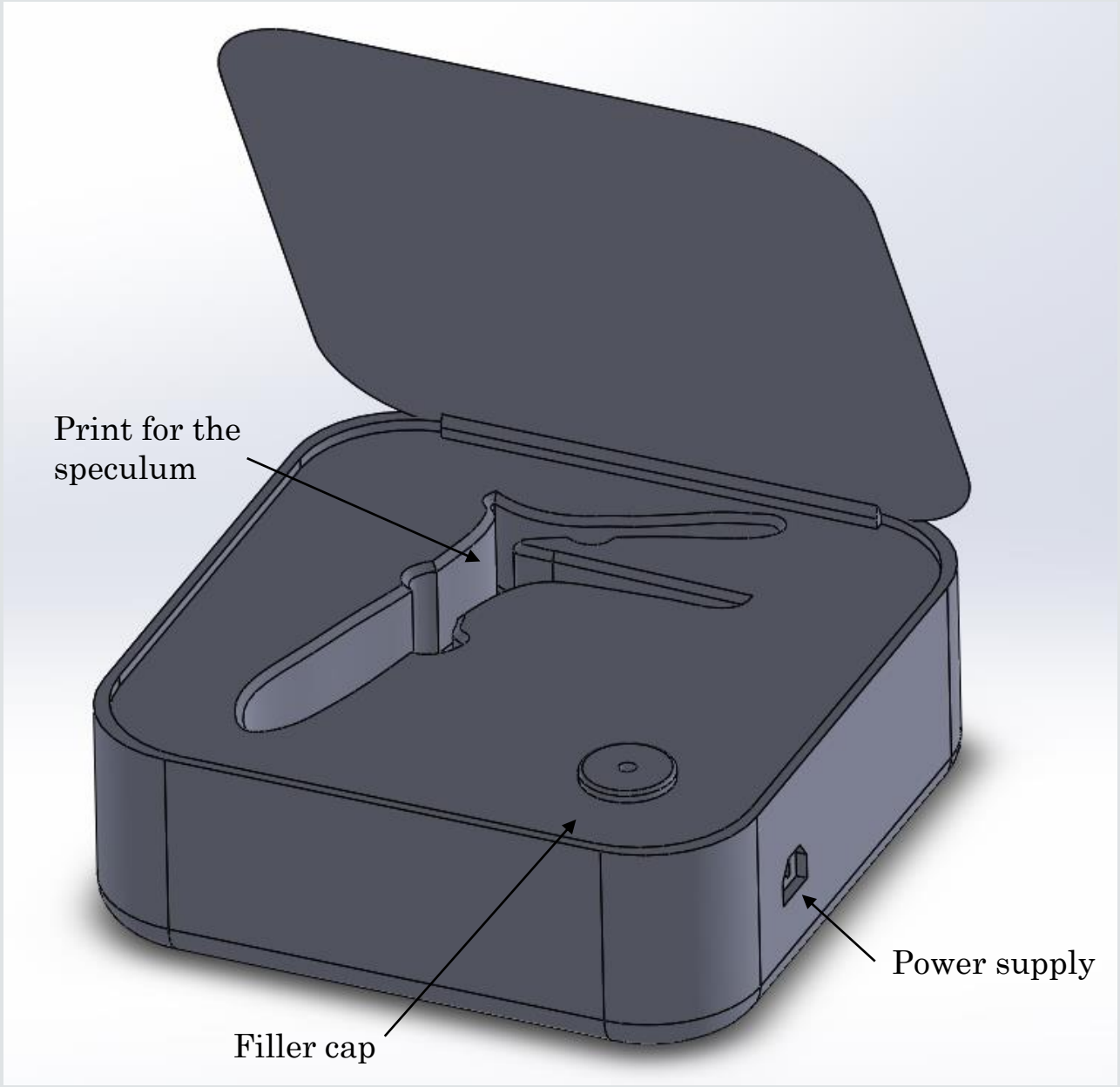
- So I came to the lying position in my bed. My back was slightly elevated by a pillow and I quickly realised that taking the speculum in the right direction but towards me was unwieldy (see photos below).
- So I turned the speculum over and realised that the device held better but my hands. As for the vision, I just had to attach my phone to the stand so that the camera on the screen side could be used as a mirror and also as a camera during the inspection.)

Bad position

Good position

4 Blades prototype

- For the third prototype, I again used modelling clay while adding cardboard for the rigid parts, notably the two additional "blades".
- I realised that the two real problems with this solution lie in the choice of the stiffness of the blades, but also in their design.
- The wrong choice of stiffness could see the blades bend and no longer perform their role. The latter could risk injury or create an even less comfortable product for patients.
- The real advantage is simply that additional slats would not add to the complexity of sterilisation, unlike the choice of transparent walls.



Sterilization box

- This draft drawn with Solidworks made me aware of several challenges with such technology. Firstly, I changed the location of the water tank so that it was in the box and not on the lid.
- But the real question it raised was whether the transparent wall part should be sterilizable or just usable once? This is a complex question that I would have to answer if I chose this technical solution.

3 main concepts

Tampon design	Transparent wall design	4 Blades design
• Cheaper • Doesn't look like a speculum • Hard to produce • Risk to be single use due to difficulty of sterilization	• Good vision on sides • Sterilizable • More expensive due to change of transparent walls	• Easy to implement • Easily sterilizable • Cheaper than the transparent wall design • Risk to be uncomfortable for patients

Ideation outcome

- This ideation phase allowed me to bring out four main ideas that are not entonomic. The sterilization box is in my opinion a good solution that can be applied to any of my speculum ideas.
- The self-use is also a plus that if I can develop it by a simple addition of a support would meet one of my needs without constraining my design too much.
- The sticking point is how to prevent the walls of the vagina from cluttering up the speculum's mouthpiece. That's why I decided to work on the shape of the speculum now, not excluding either of the two ideas. I could then test them on my final design, always taking into account the need for sterilization.

Prototyping

- This part is dedicated to create prototypes and 3D visualizations for the 2 main solution.

How to design the new speculum?

- My strategy for developing an ideal speculum for the new speculum was to focus first on the shape of the product itself before testing the possibility of adding transparent walls or the two extra blades.
- The study will therefore focus on three four points: the shape of the spout, the shape of the handle, the technology for opening the speculum and the technical choice for the wall problem.
- Firstly, I decided to deal with the shape of the spout before tackling the task of the handle and finally the opening system and the protection of the walls.
- For this I used Solidworks software to produce as many 3D designs as possible.
- However, this software is commonly used for volumetric models and is quickly complex when one wants to work on surfaces. I had to face a lot of construction errors, here on the next page.
- These were present throughout my work and greatly reduced my progress, although as time went on I understood better where they came from and how to solve them.

Analyze of Bugs

- There are different types of errors and each one needs to be analysed carefully in order to understand what they are about. The three main ones I encountered are:
- Construction errors →The sketch could not be updated because solving it would result in invalid geometry (such as a line of zero length)
- Object conflicts → The sketch has conflicts. Consider removing some over-constrained features or relationships.
- Wobbly geometry → This sketch contains dimensions or relationships to model geometry that no longer exist.

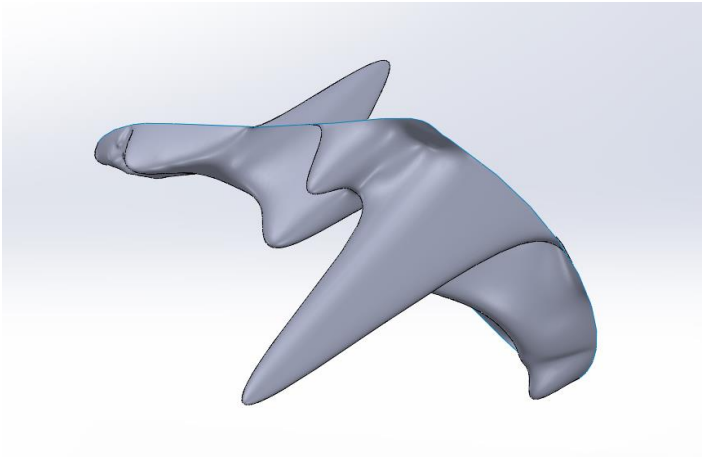


Fig. 7 Construction errors

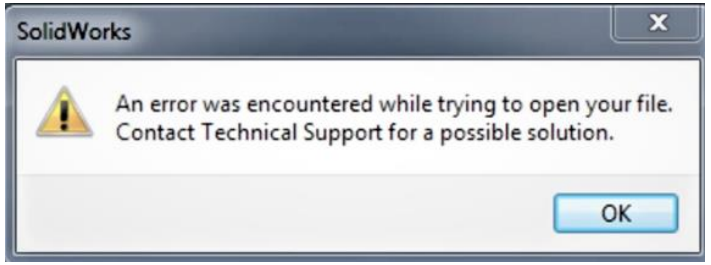


Fig. 8 Object conflicts

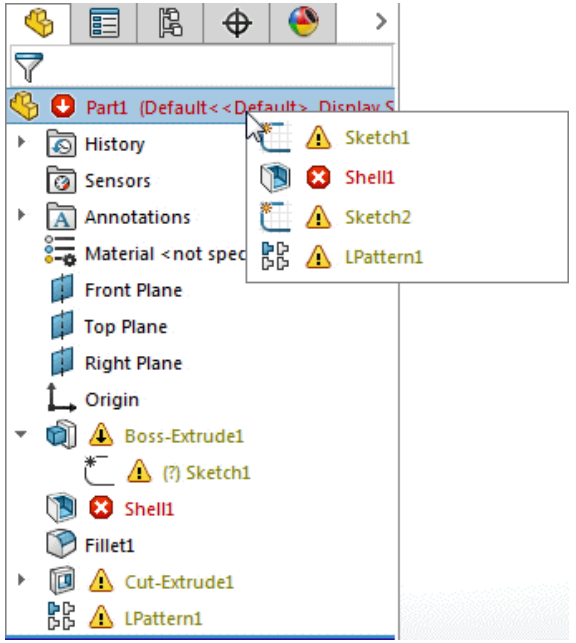
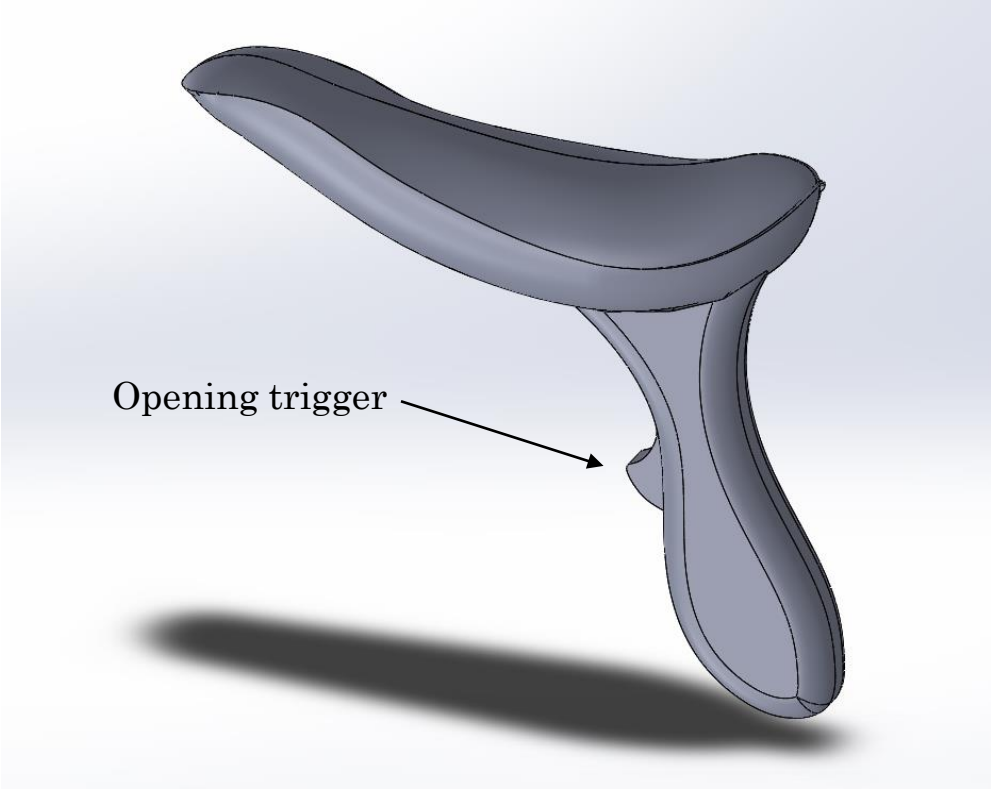
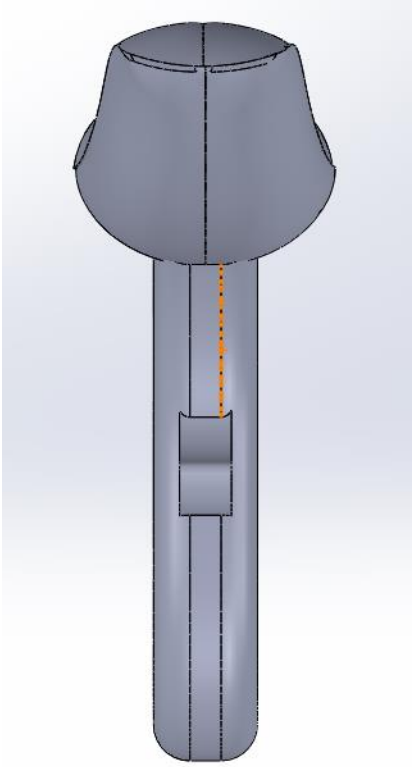


Fig. 9 Wobbly geometry

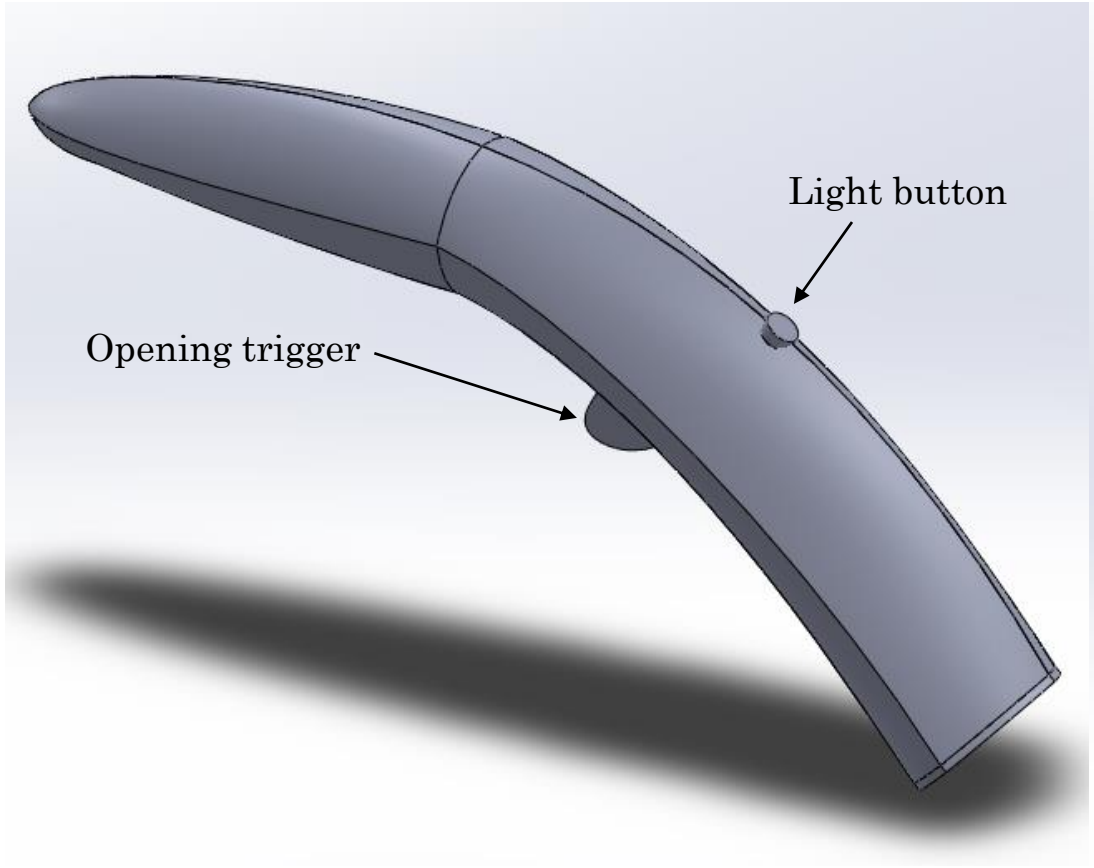
Concept n°1

- For the first design, I sought to produce something very different from the original design. The aim was to create a more harmonious structure that did not resemble an instrument of torture while still allowing the clinician to use it with maximum efficiency (the observation hole is missing).



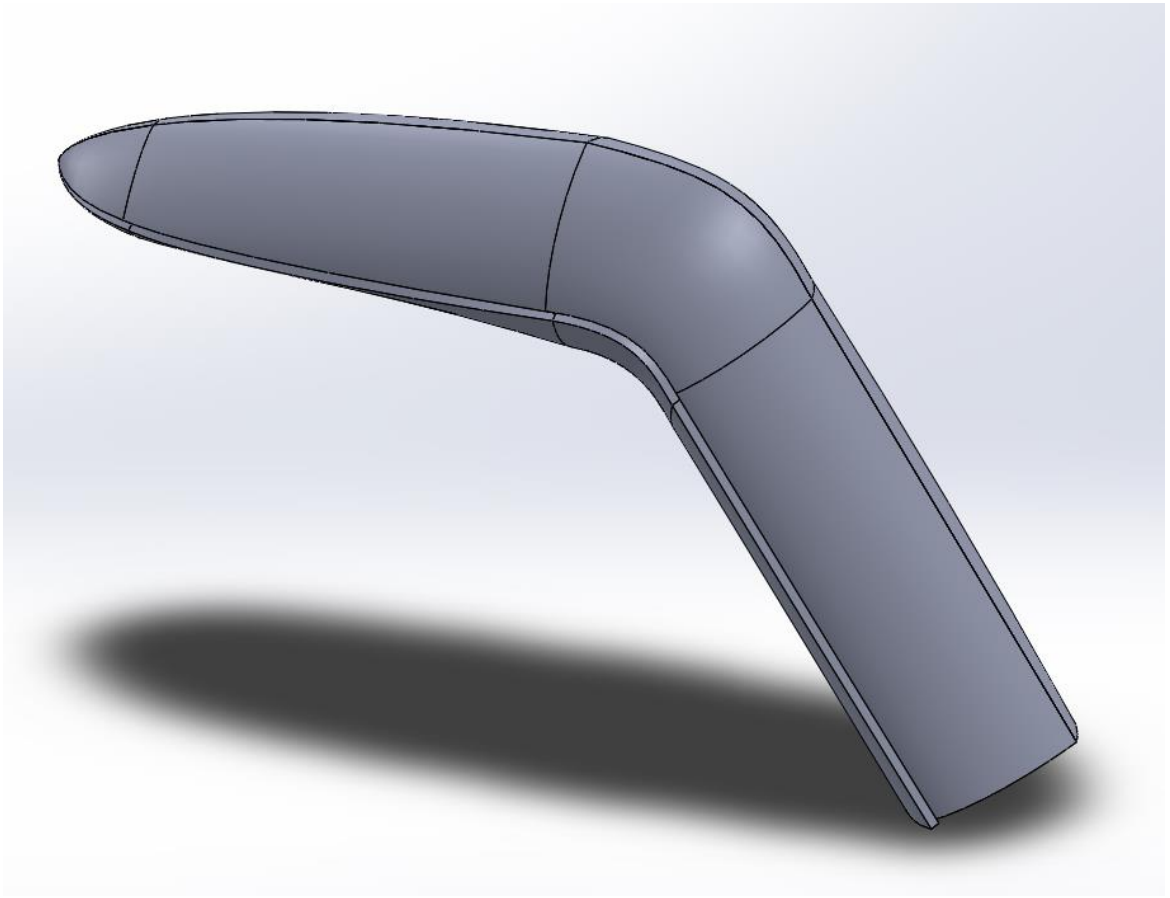


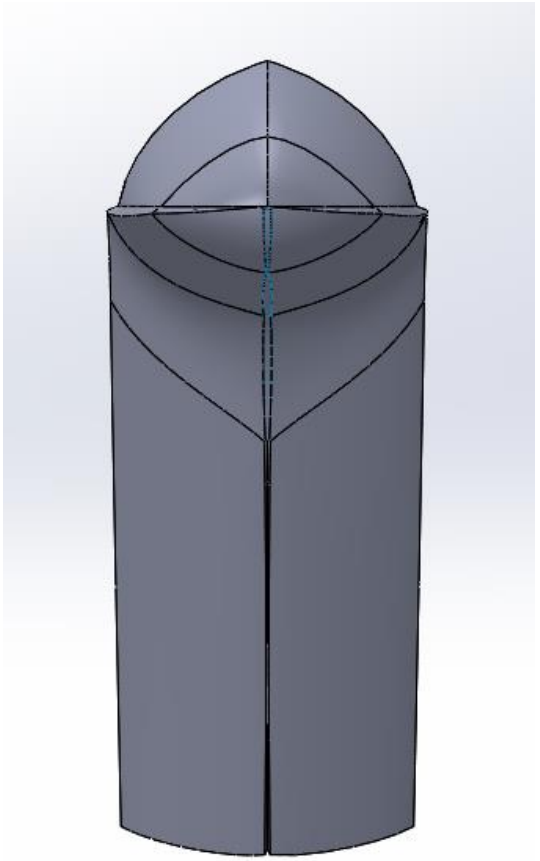
Concept n°2



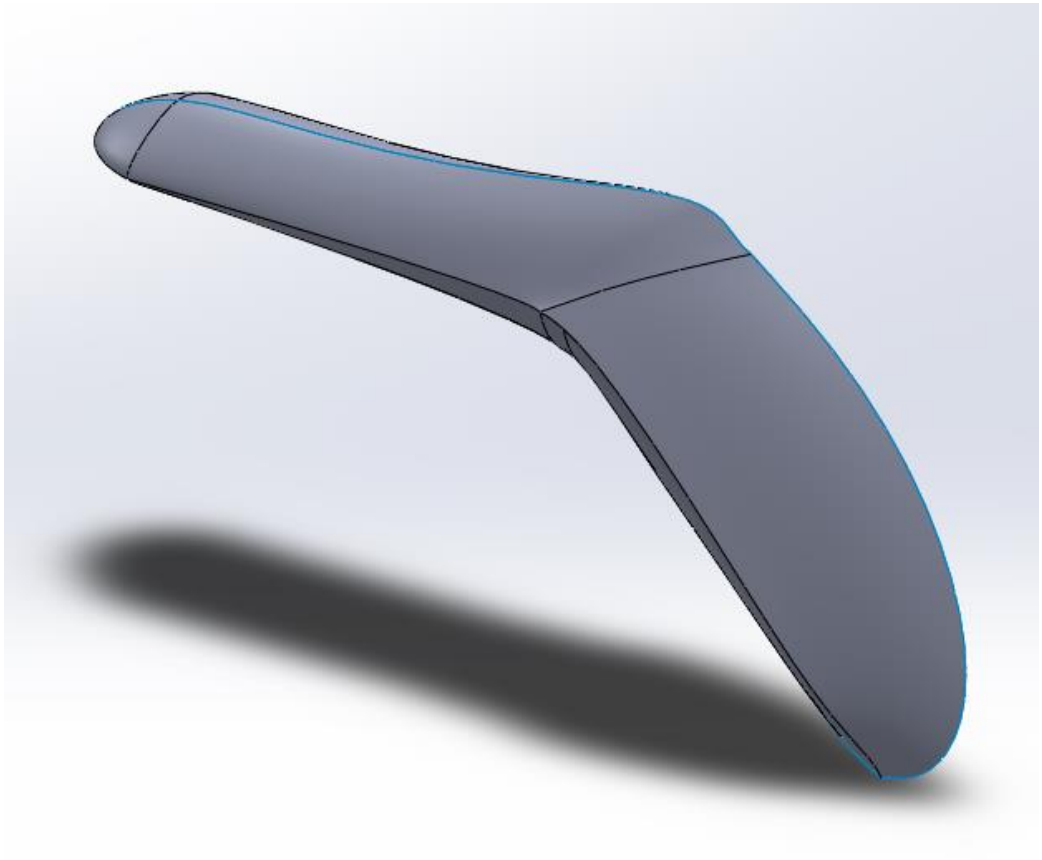
- Concepts 2, 3 and 4 are more attempts than real concepts. This is due to the complexity of the software used and the way in which the model has to be built, which is different from the volumetric models I used to produce.

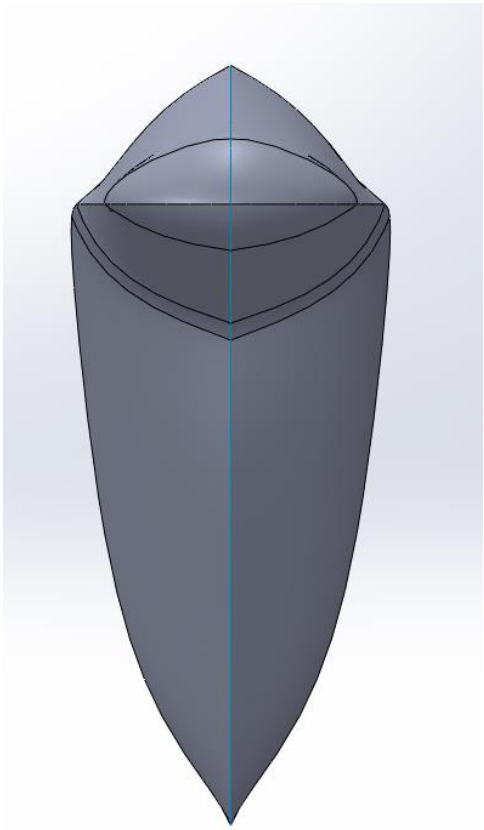
Concept n°3



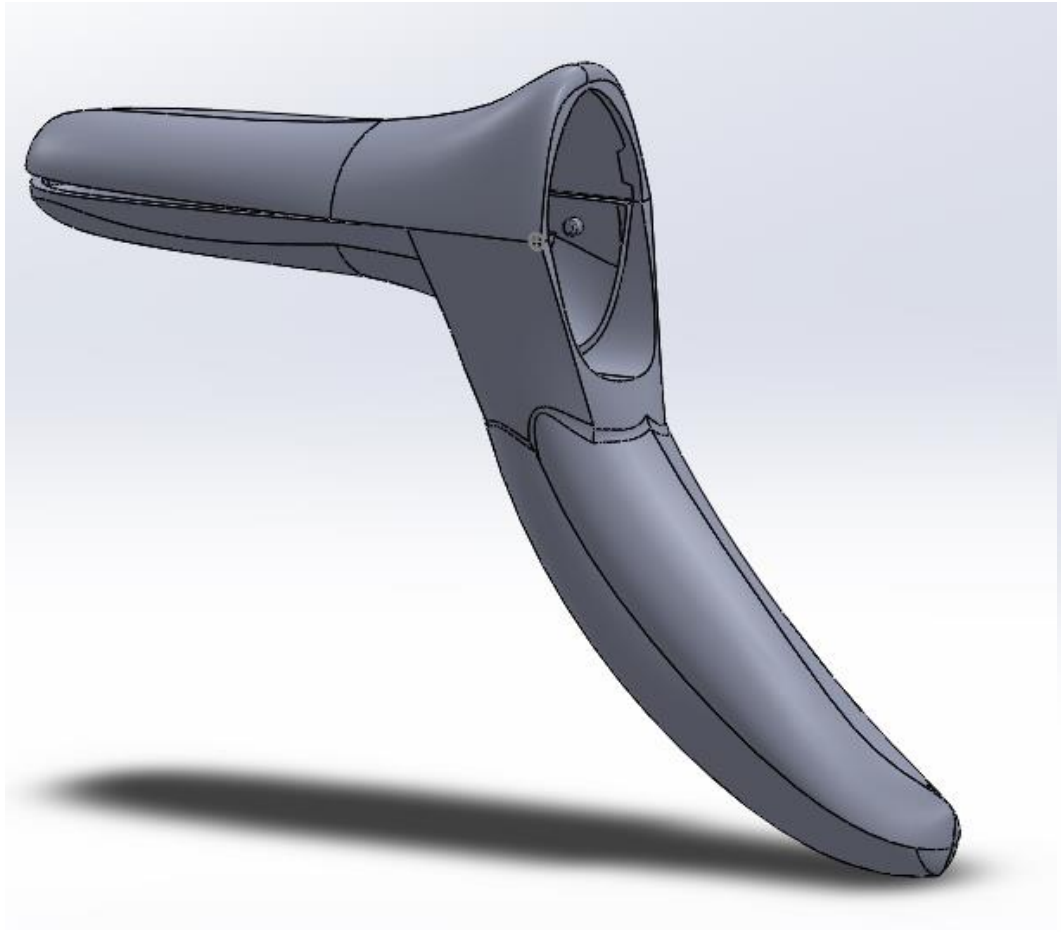


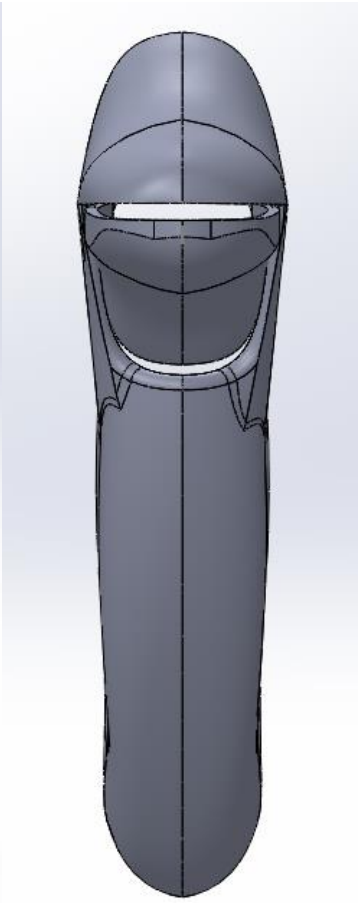
Concept n°4





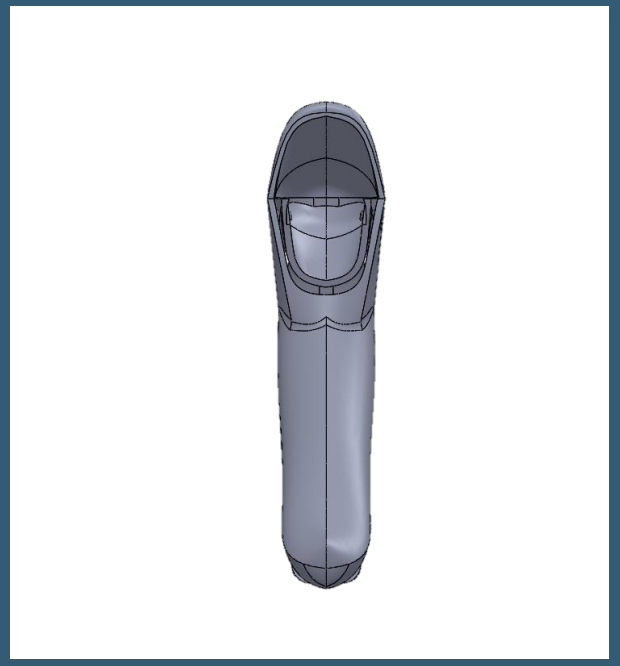
Concept n°5





- Here is the first concept that looks like a realistic product. In finally producing a product skeleton, I identified that I would need to work on several key points:
- The handle
- The opening system
- The shape of the spout
- The system to protect the walls

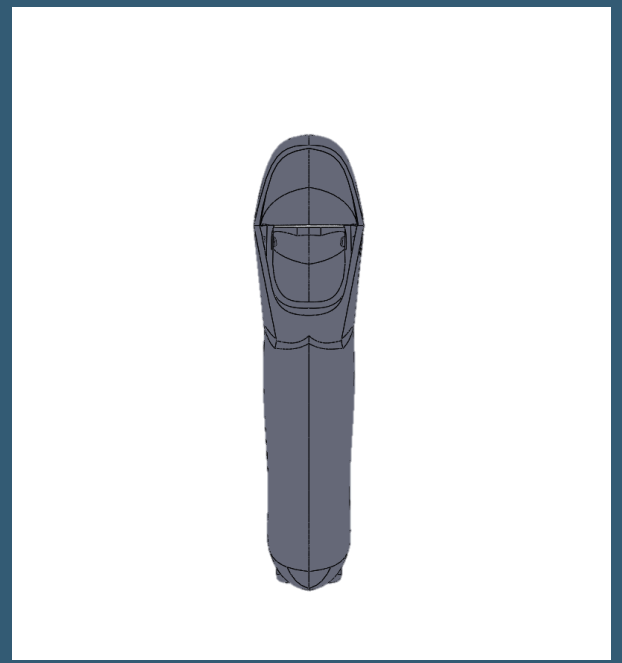
Handle prototypes: Printed version



Concept n°6

This concept sees the introduction of the speculum opening system. This is simple with a pivot allowing the user to open the spout with a simple push of the hand.

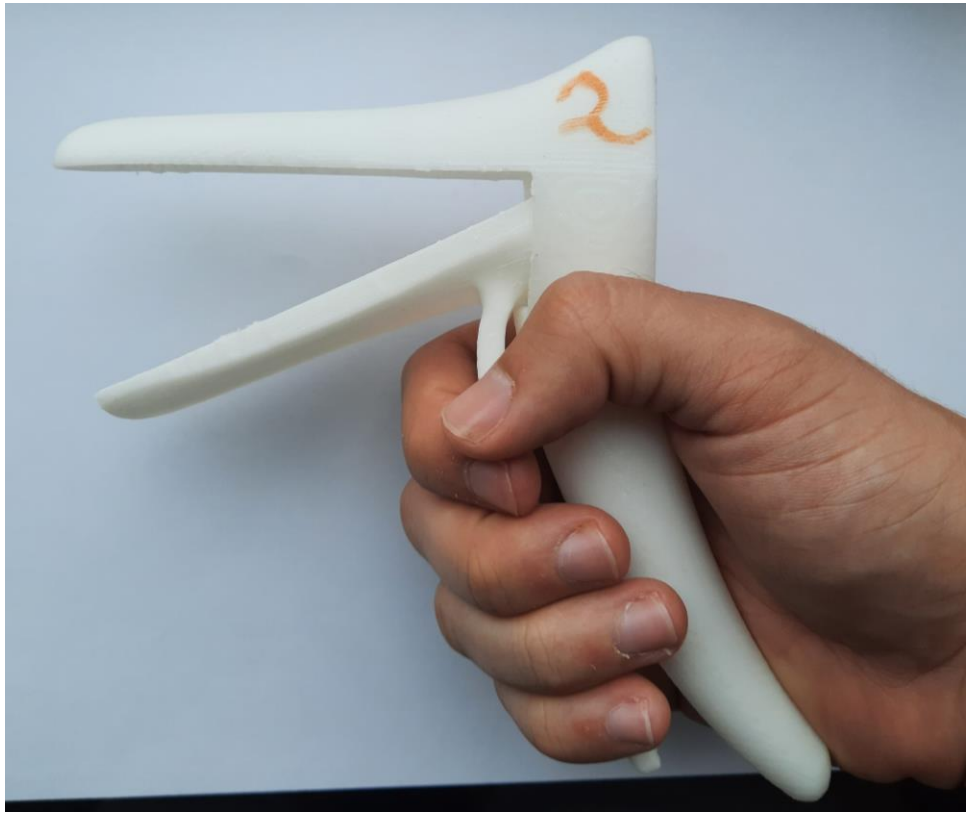
Concept n°6: Printed version



Concept n°7

This seventh concept has only one slight change to the trigger. I've added some leaves and changed the shape to be more curved.

This way it feels better in the hand.



Concept n°7: Printed version

Concept n°8

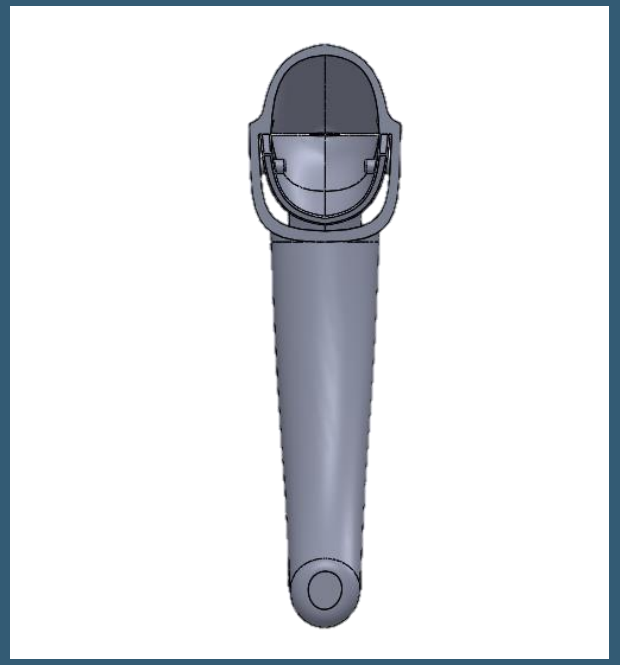
- While printing my first prototypes, I realised that my design is not comfortable for all hands.
- Indeed, I had my three roommates test it out, each with a different body type, and smaller hands don't feel comfortable with the product in their hands.
- So I decided to modify only the handle to solve one problem at a time.

Concept n°8: Printed version

Concept n°9

- After several attempts with my 3D printer, I have produced a handle that is more comfortable for the user.
- It seems that the curvature of the handle should not be too important because it does not allow a good grip for small hands.
- 3D printing allows you to quickly produce several different handles while keeping the rest of the product the same.

Concept n°9: Printed version



Concept n°10

- This design shows the handle that all three of my testers agreed on. I then modified the speculum's mouthpiece to resemble those currently on the market.
- For this, I took inspiration from two speculums currently used in hospitals in Ireland.
- In addition, I continued to discuss with some of the gynaecologists I had interviewed to establish the specifications.
- They reminded me of the importance of the rounded shape at the end of the speculum's beak to avoid disturbing the patient too much during insertion.

Concept n°10: Printed version

Inspiration

- To draw the beak, I was inspired by several speculums, including these two which are currently used in the St John's maternity hospital.
- The characteristics I kept are:
- -The rounded tip of the beak
- -The dimensions: width and length
- -The profile that widens as you go along
- -The thickness

Concept n°11

- For concept number 11, I took care to add a locking system in position as is necessary for clinicians.
- The technique is simple, a screw and a nut. The real technicality lies in the position of the system so that it does not interfere during the operation.
- This is why I decided to produce a new concept because the screw in the open position is far too awkward for the user.

Concept n°12

- Concept 12 is the final concept before adding either a transparent wall or extra blades on the sides.
- For this, I decided to test a fake vagina that I will produce with my 3D printer and foam.
- The interest of this concept is that it meets all the customer's needs while leaving the possibility of future modifications after the tests have been completed.

Concept n°12: Printed version

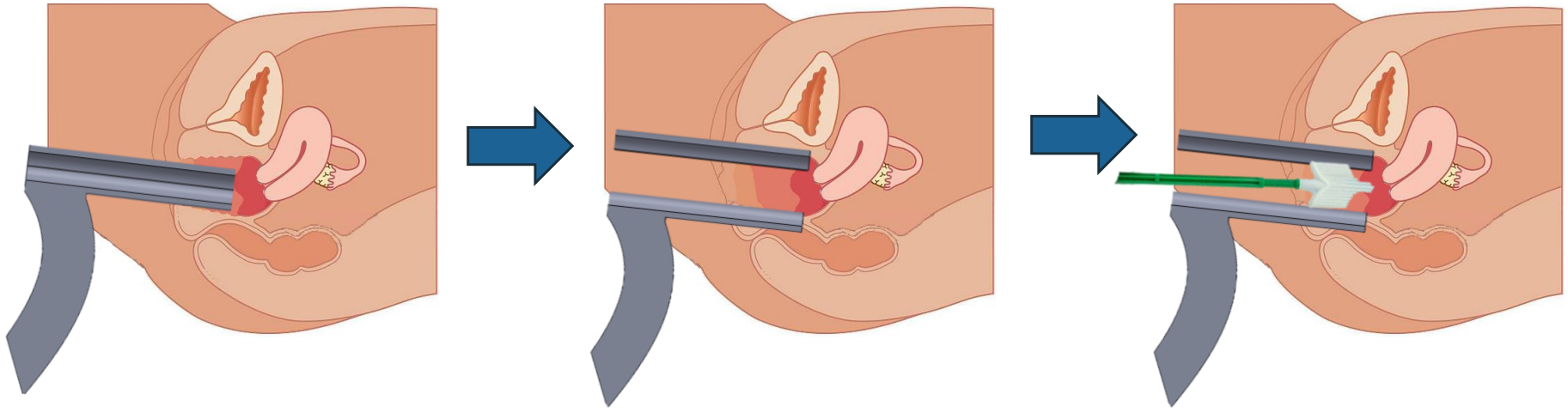
How to choose the opening system?

- One question that was asked of me and which I had to look for the answer to when I hadn't thought of it was: Why keep an opening system similar to a beak and not rather a cylinder that would spread out in the female organ.
- The first answer that came to my mind was that the choice of a cylindrical opening was archaic and that this was why it was decided to stop producing specula with this technology.
- However, this is not a scientific answer and that is why I asked three gynaecologists directly for their opinion.

How to choose the opening system?

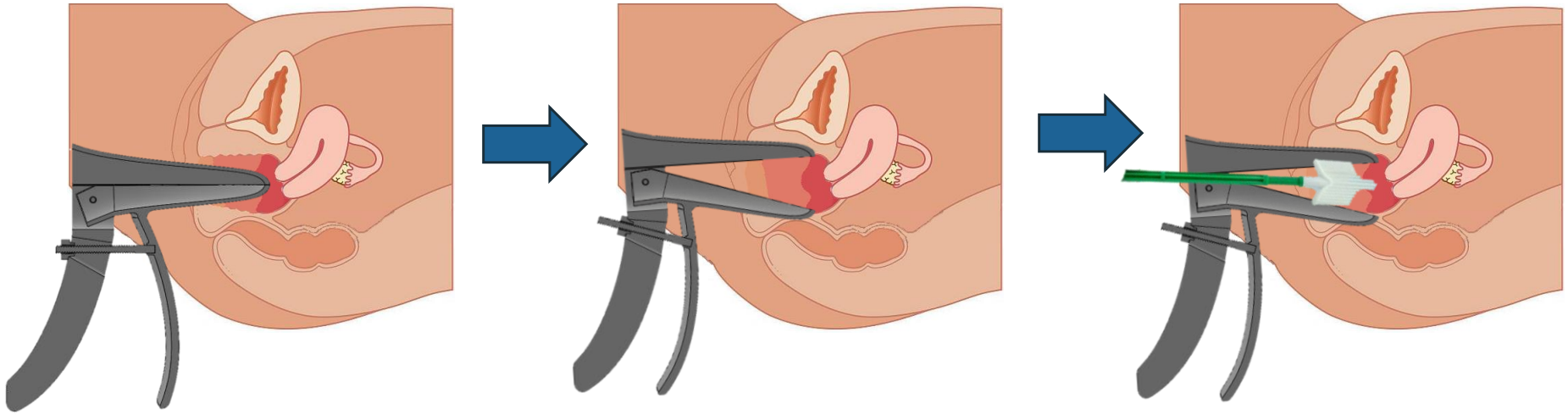
- So, I asked them: What is the best opening technique between the beak and the cylindrical one?
- Their answer was unanimous. It was based on two facts:The first is that a beak opening is less uncomfortable for the patient because the cylindrical opening involves widening the whole vagina and not a little at a time.
- Secondly, gynaecologists may only want to open the speculum slightly while introducing their medical tools with which they need to operate. With a cylindrical opening, this would require the speculum to be opened wider because the diameter is uniform.
- To visualise this problem, I have made a storyboard shown on the following slide.

How to choose the opening system?



- Here you can see the storyboard of a smear test with a cylindrical speculum. As you can see, this involves opening the speculum wide so that the clinician has the range to work with during the smear test in this case.

How to choose the opening system?

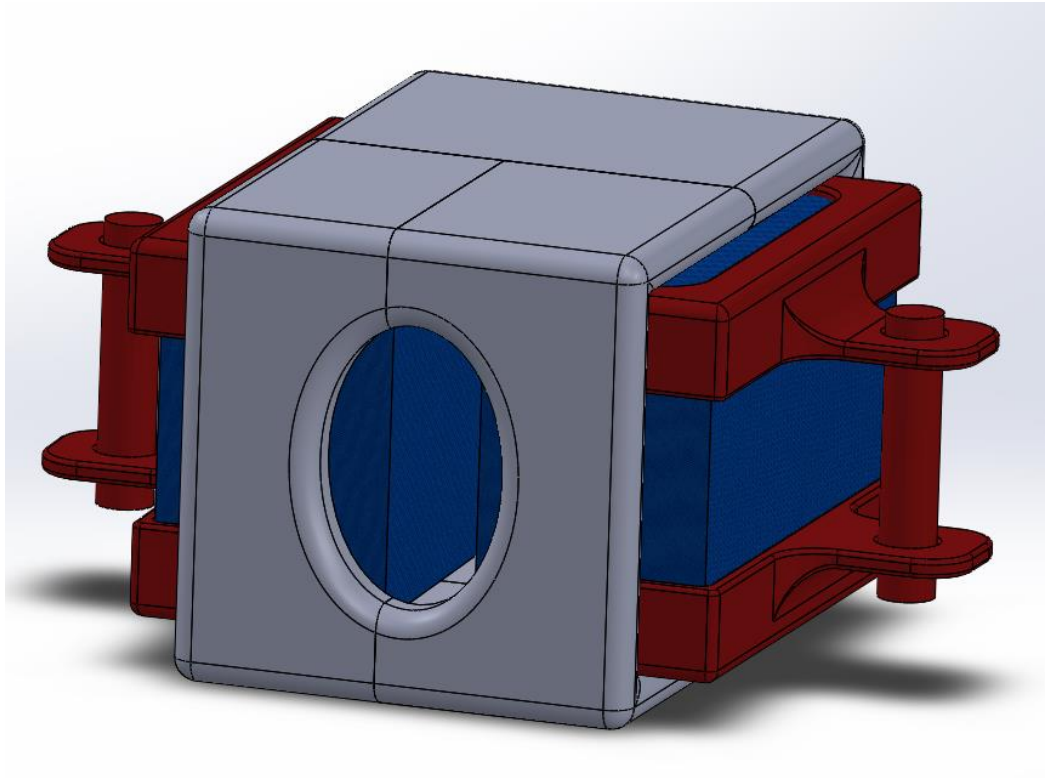


- In the case of the beak opening, the clinician does not need to open the product wide to perform a smear test. This makes the procedure more comfortable for the patient.

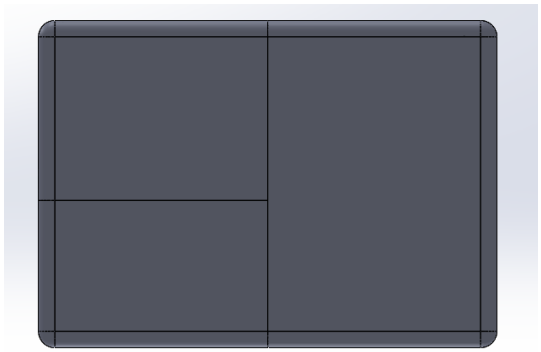
Testing

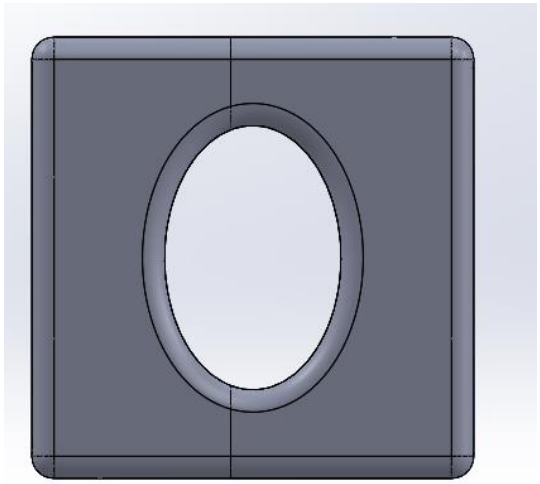
- This part is dedicated to describe of I tested the product to find the best design to answer client's needs.

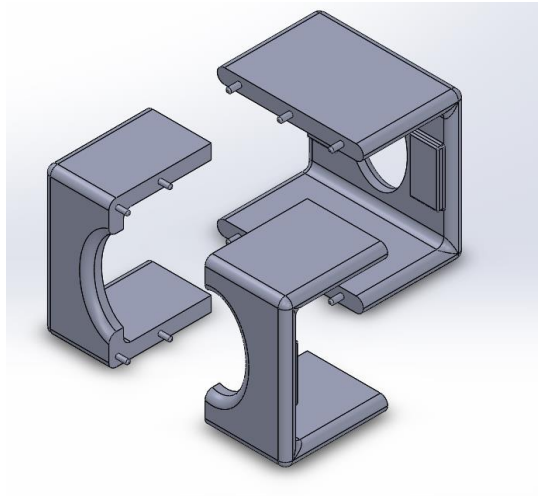
Test module

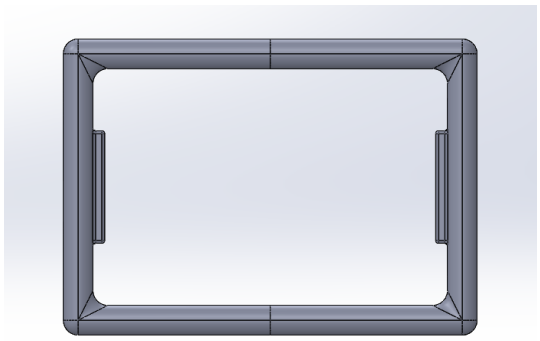


- To evaluate the functionality of my prototype, I decided to produce a test as close to reality as possible. To do this, I created a module that is supposed to reproduce the female organ.
- It is composed of a casing (grey part), a support allowing to vary the width of the walls (red) and a foam (blue part) which represents the walls of the vagina.
- The latter is stiffer than a sponge and allows us to test whether the speculum can see into the bottom of the housing, representing the cervix.



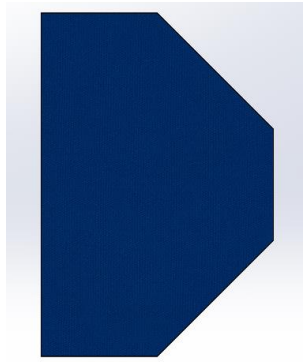


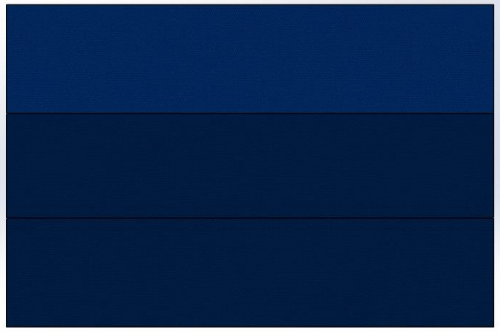


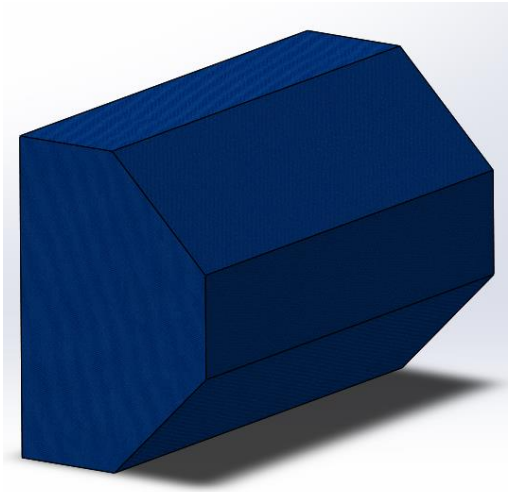


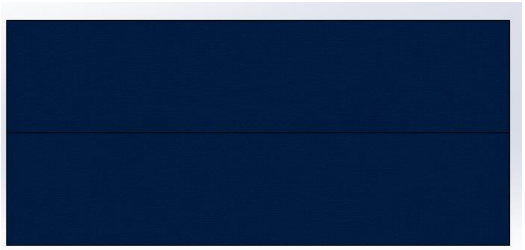
“Female organ”

- To produce this device, I once again used my 3D printer. In order to overcome size and printing time concerns, I divided the casing into 3 parts.
- The system allows to easily change the foam to test several cases as it is the case in the field.
- That's why speculums generally come in three sizes: small, medium, large and sometimes even a fourth size, this time longer.









“Female organ”

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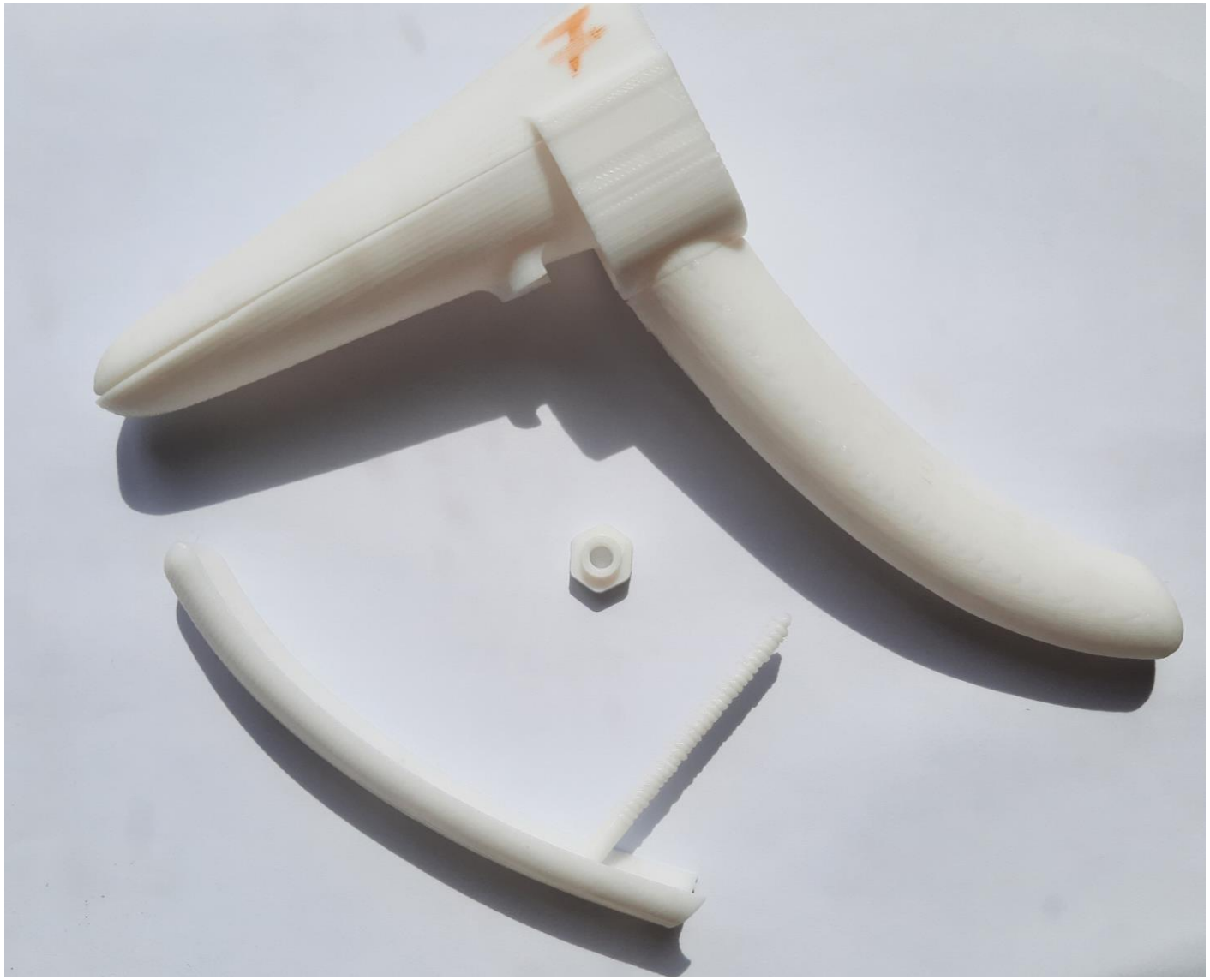
First test

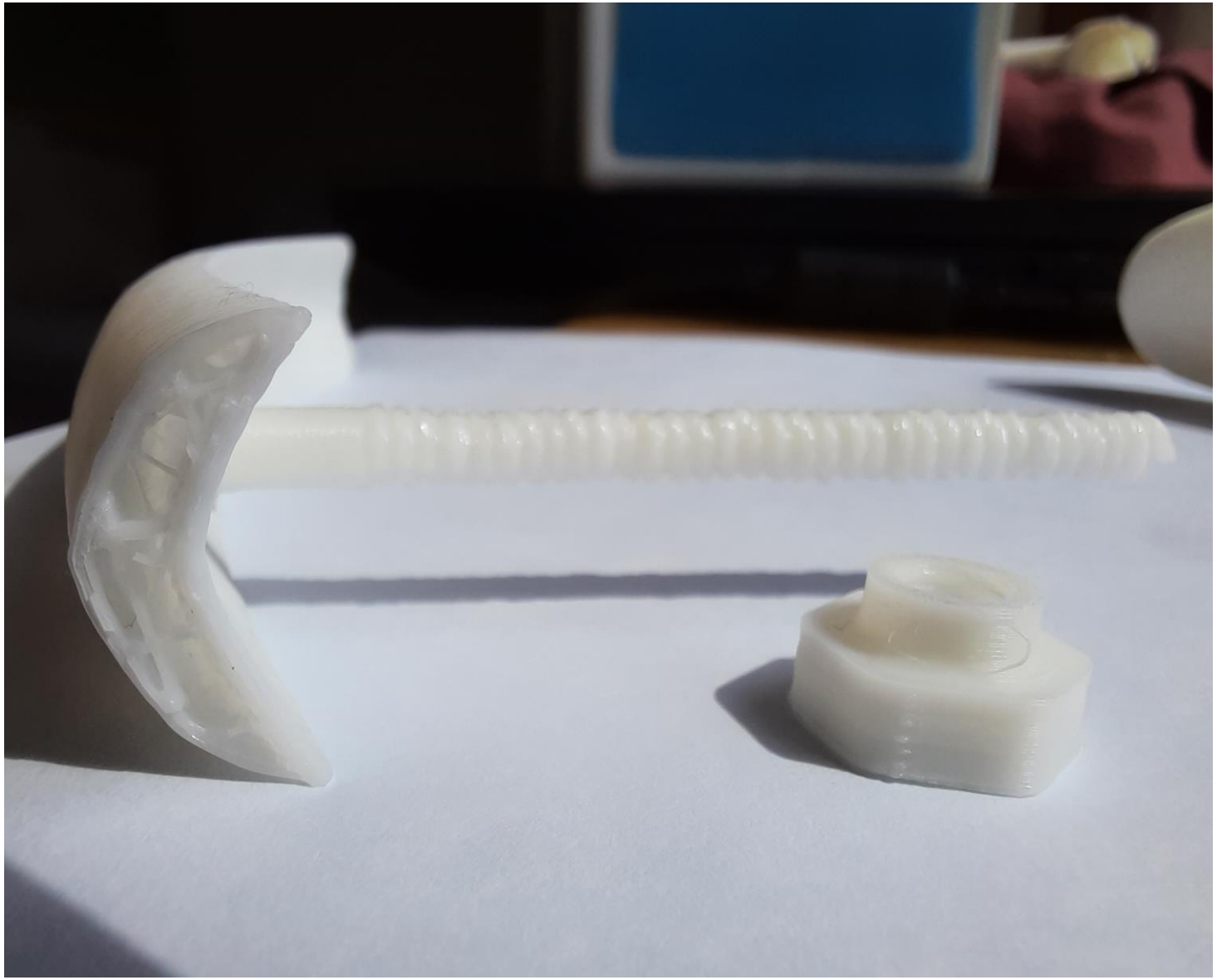
First test

- This first test is simply to highlight the problem that clinicians face.
- As you can see, the blue foam that is supposed to represent the walls of the vagina fits into the beak of the speculum and obstructs the vision.
- A second variation of the foam cut-out will then be tested to further accentuate the problem to see the difference with the two possible solutions: the transparent walls, the additional arms.



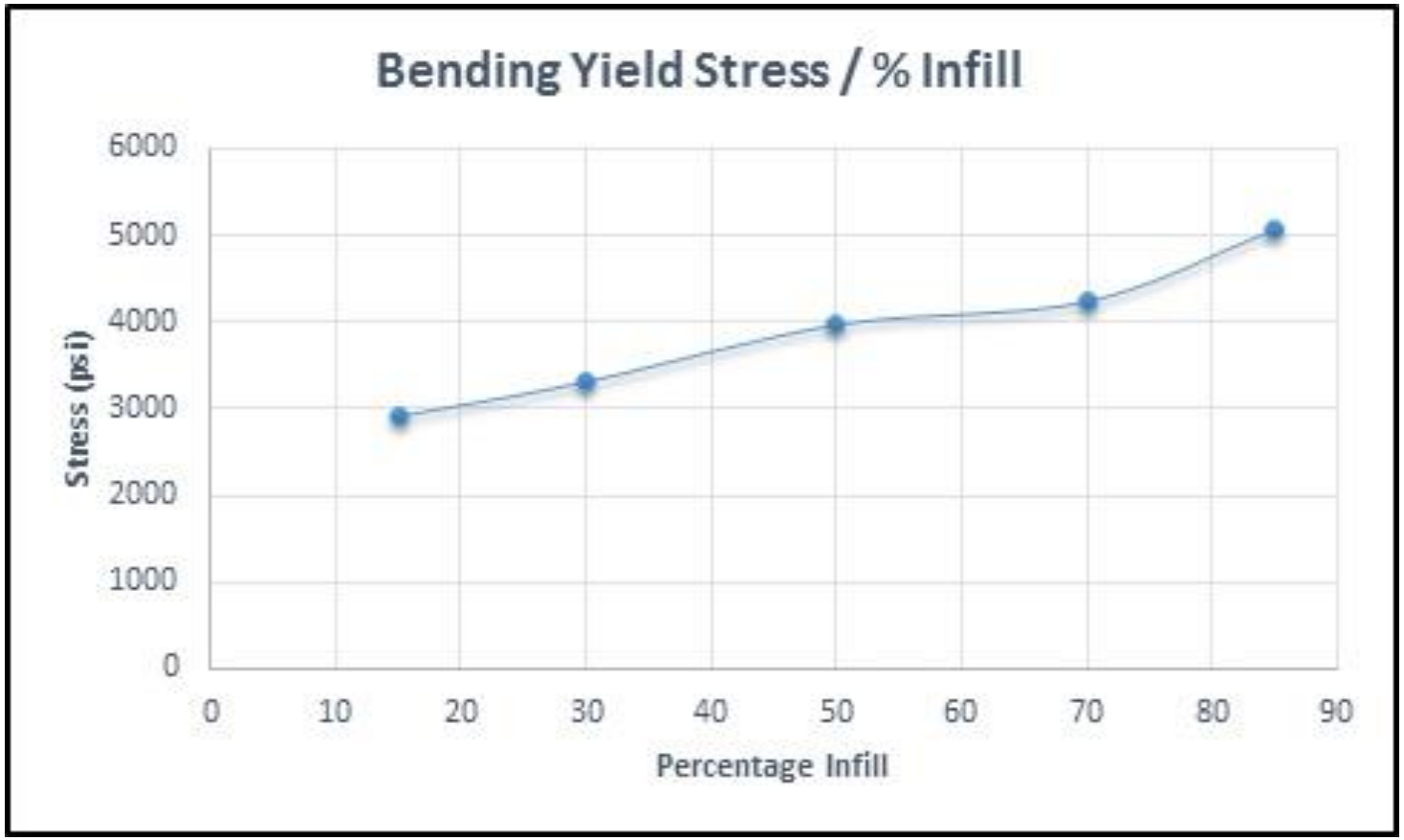
Second test

- On my second attempt, I wanted to increase the amount of foam in the module to represent a woman with a less broad vagina.
- Unfortunately, the speculum didn't hold and the trigger part broke off cleanly just as I opened it.



Second test

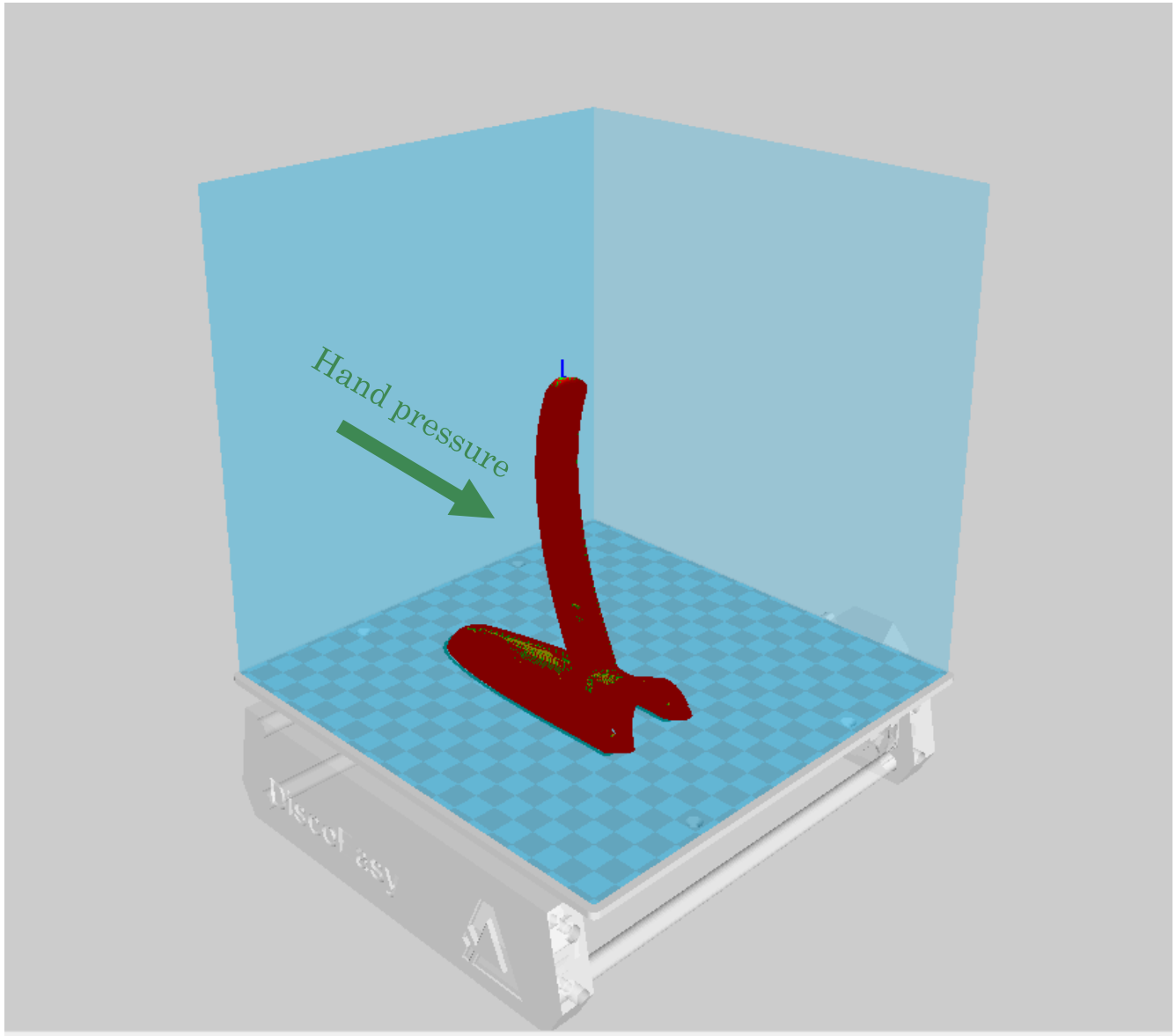
- **Why did it fail?**
- I tried to understand where the problem came from because such a malfunction is unimaginable during an operation.
- It is by observing the place where the breakage occurred that I understood where the problem resides. My prints are never 100% full. This one was only 15% full to save time when printing.
- This reminded me of the studies I did in engineering school with the mechanical resistance depending on the fill rate.



- *Fig. 16 Mechanical Testing 3D Printed Parts: Results and Recommendations from* EngineerDog.com. (2015)

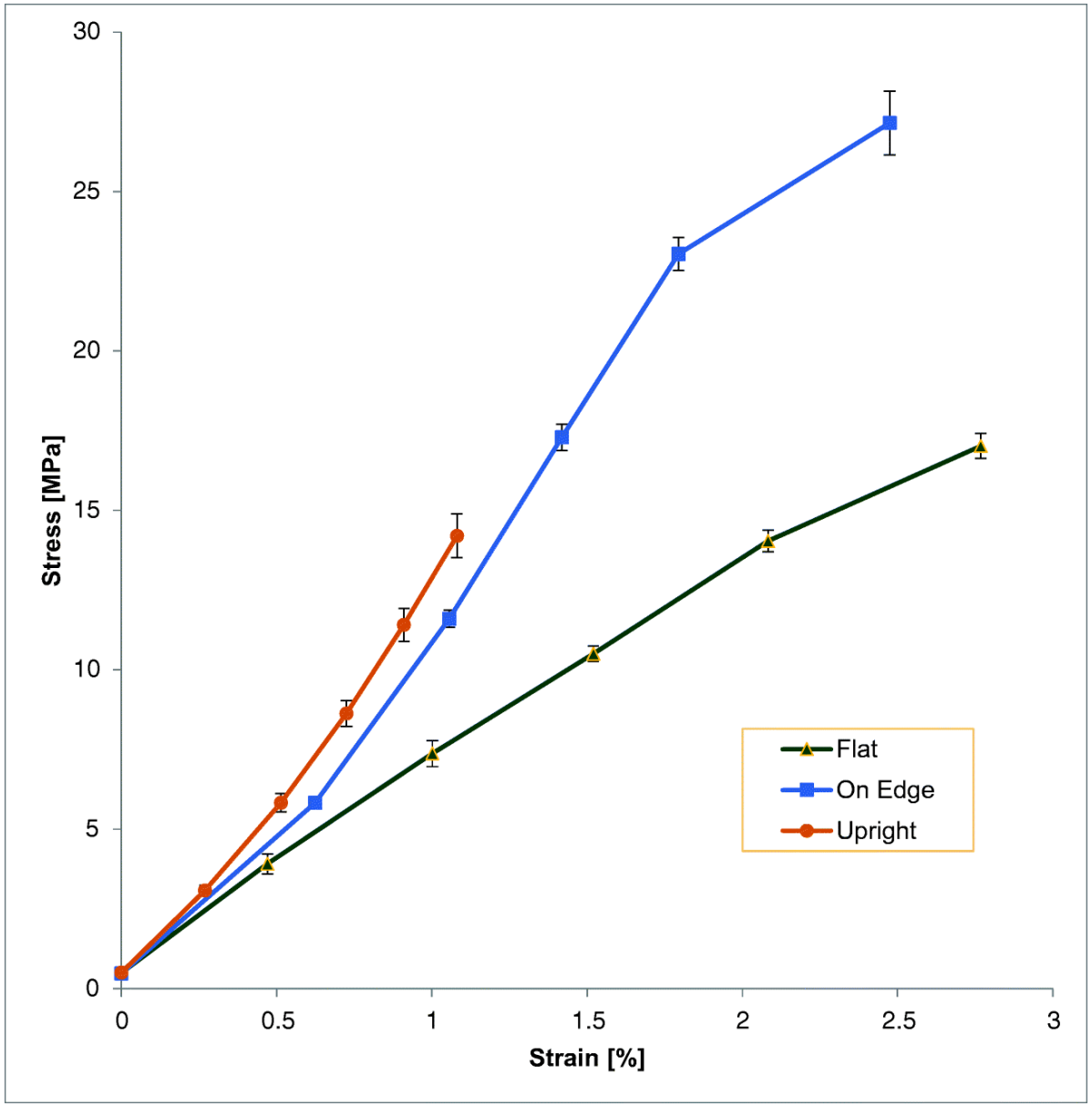
Second test

- **Why did it fail?**
- As you can see from this graph, the mechanical strength varies with the fill level.
- However, doubling the fill level does not double the mechanical strength.
- Especially since a second parameter comes into play.



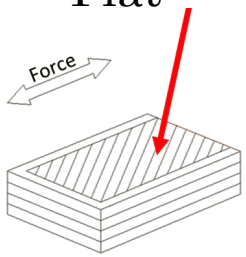
Second test

- **Why did it fail?**
- This second parameter is the orientation of the printing direction. Here, the trigger has been printed vertically. This means that the successive layers are deposited horizontally, and it is they that will oppose the force of the hand when we try to open the speculum.
- In this case, the only resistance produced by the trigger is the adhesion between each layer and not the resistance to the filament's fusion.

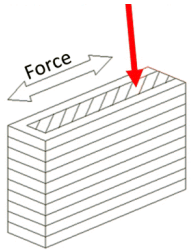


- Effect of print orientation on mechanical properties

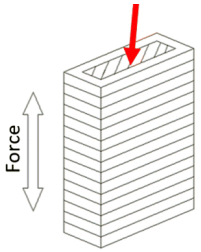
Flat



On-Edge



Upright



Second test

- **Why did it fail?**
- To support this, here is a study (Hanon et al. 2020) showing the difference in mechanical strength for the same amount of filling by varying the orientation of the wire print.
- It is easy to see that their tensile strength and flexibility vary according to this second parameter.
- This is why I decided to reprint my trigger by changing its orientation to validate my theory. If the trigger fails again, the model will have to be modified to compensate for the fragility of this part of the model.

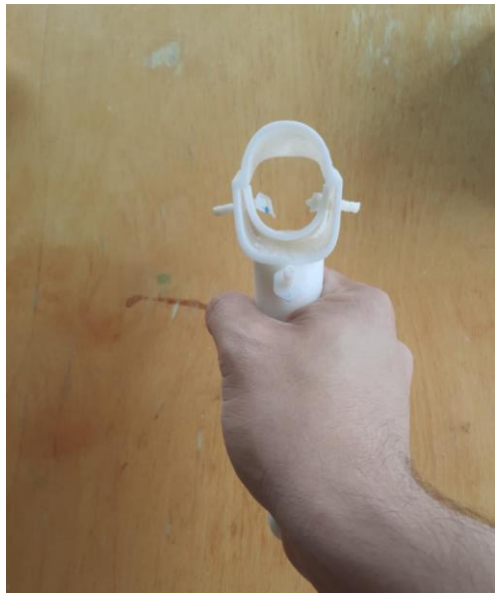
Third test

- This third test was carried out with the help of Dr Dan Borlase. He gave me a precious help in testing the product. He gave me several suggestions for improving the product, along with some advice:
- Speculum transparent is good but it is not a must in comparison of the rest (e.g. light, new handle, …)
- Add a light at the start of the product is really important but it needs to let space for the clinician to work
- Speculum can be use in both position (Handle up or down)
- Screw is a good solution because you can choose exactly the position and you can change it easily with small changes. So, avoid preset positions because you don't have this flexibility.
- In case of bleeding (especially miscarriage) and SROM (spontaneous rupture of membranes) the light should be on top (attention to the position of use) due to the fluids coming out
- Dislike the idea of additional arms for two reasons, could hurt the patient and it will obstruct the vision of the clinician on sides.
- If the transparent wall is the best solution: Let one centimeter of space for the end of the transparent wall (for the cervix)

Third test

- To conclude this third test, the fact that Dr. Dan Borlase has shown me that the speculum can be used in both directions makes me look at this product in a new light.
- Fortunately, the design as it stands works for both uses. Nevertheless, it should be kept in mind for the rest of the tests and for the improvements to be made to the design as a result of this investigation.

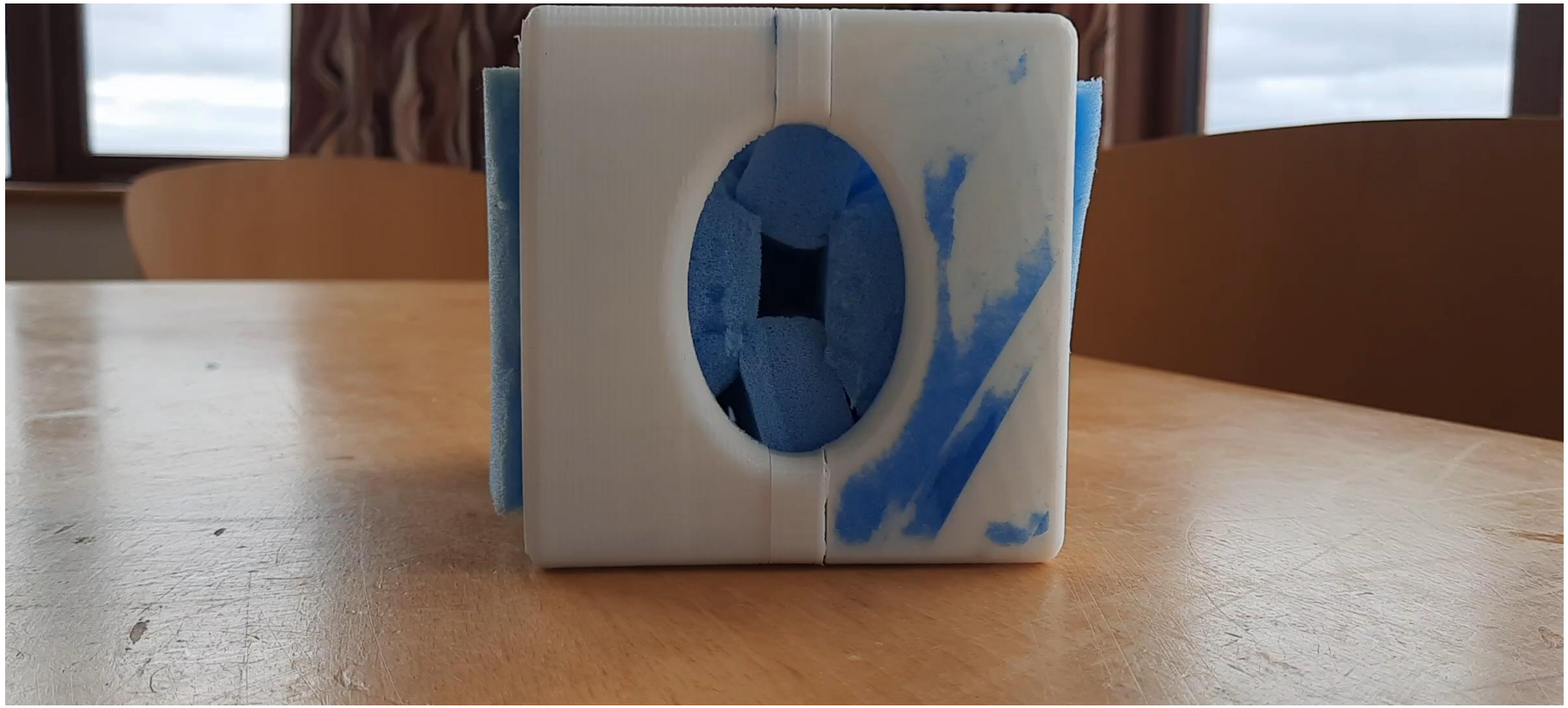
Fourth test



Fourth test

- Despite Dr Don Borlase's and my own misgivings, I tested the idea of the extra arms anyway.
- As you might expect, the arms pose several problems:
- They allow foam to pass over the sides
- They force slightly on the walls of the penetration. This could cause injury to the patient
- The arms need to be linked to the opening movement to always be in the middle of the mouth to fill the space created.

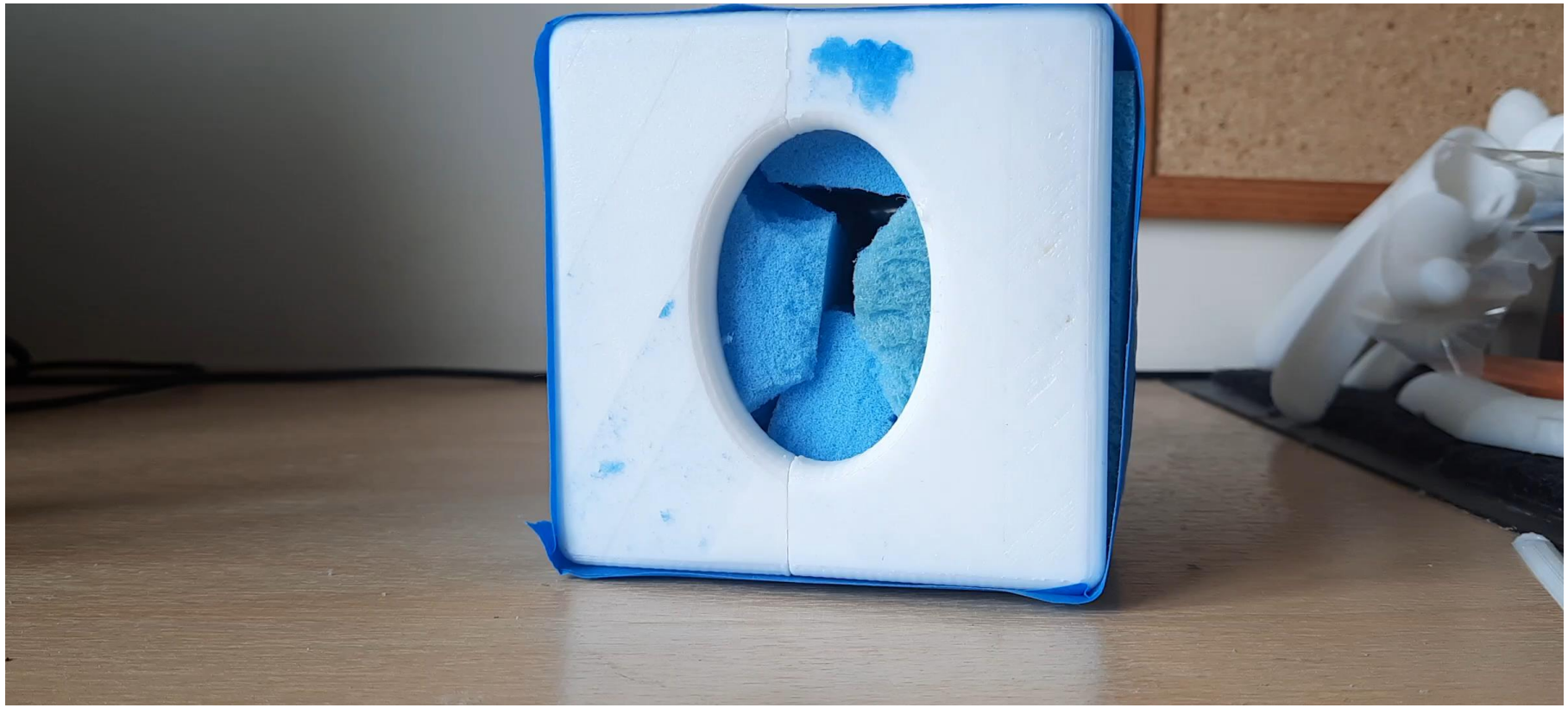
Fifth test

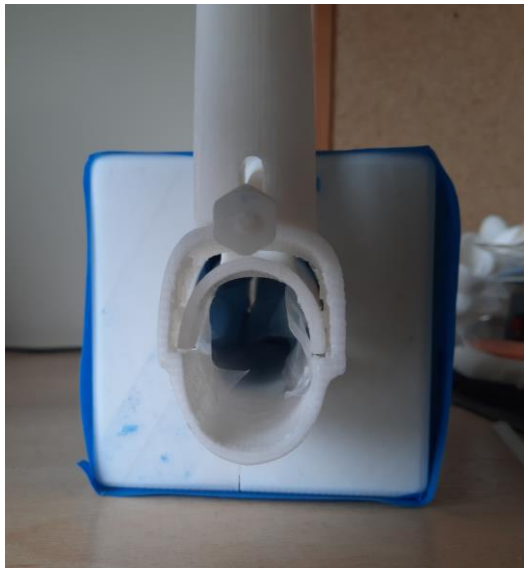


Fifth test

- As expected, the test with the condom as a transparent wall works well.
- It has the advantage that it is flexible and naturally returns to its original shape like all elastomers before you exceed their elastic limit.
- Of course, this does not mean that the future of the new speculum is to be used with a condom. It simply identifies a material that can meet our need for side protection.

Sixth test





Sixth test

- This last test was not conclusive. Unfortunately, it has the same flaws as the technique of adding arms on the sides.
- Indeed, as you can see on the picture on the bottom left, there is only a small opening at the level of the uterine cervix because the muslin goes inside the speculum by pushing the walls.
- This means that the material chosen must be elastic enough so that the clinician does not have to force the trigger to open the speculum, but rigid enough to fit against the walls of the vagina.
- Always keeping the material transparent to allow clinicians to observe the entire vagina without having to rotate the speculum inside the patient, which can be unpleasant.

Observations to problems

Observations	Problems
The handle may be too long for some users	The length of the handle may hinder the use of some clinicians
The position of the light plays an important role and can be troublesome for the clinician	The lamp at the beginning of the speculum may interfere with the clinician or fluid flow
The product could be fully transparent to facilitate the clinician's vision	As the product is not transparent, it can hide certain details of the vagina
The clinician uses the screw-nut system to have precise positions during the procedure	Clinicians do not want to have a locking system with predefined positions
The extra arms allow the walls to pass and ripple along the walls	Additional arms do not meet clinician/patient needs
Transparent walls work but require a careful choice of material and shape	Walls that are too soft allow the vaginal walls to pass into the speculum, walls that are too rigid would reduce the comfort of use

Problems to needs

Problems	Needs
The length of the handle may hinder the use of some clinicians	Reduce the length of the handle
The lamp at the beginning of the speculum may interfere with the clinician or fluid flow	The placement and the side of the light should let space to work and let fluid flow
As the product is not transparent, it can hide certain details of the vagina	The product could be transparent
Clinicians do not want to have a locking system with predefined positions	The locking system should give a free choose of positioning
Additional arms do not meet clinician/patient needs	Don’t add additional arms to the device
Walls that are too soft allow the vaginal walls to pass into the speculum, walls that are too rigid would reduce the comfort of use	The transparent walls must face properly the issue of walls prolapsing without reducing the comfort of use

Conclusion test

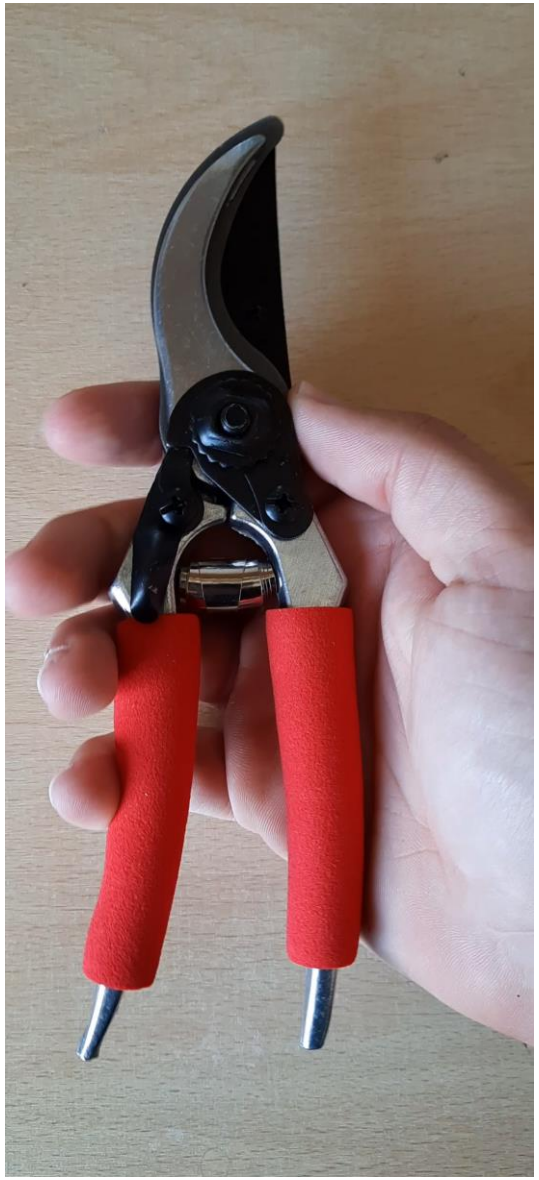
- These few tests have brought many answers but have also added needs to which I must find solutions in this final phase of design.
- 1. Validate the fact that there are no better techniques than the screw-nut to choose the locking position of the spout
- 2. The next task is therefore to produce a CAD to describe exactly what the transparent walls look like.
- 3. Next, add a lamp that will need to be sterilisable like everything else in the product, but still allow for possible body fluids to spill out
- 4. Find and validate a solution for the sterilisation box
- 5. Finalise the design of the product so that it can be produced industrially in large quantities

Final design

- This part is dedicated to the final step of modification of the design before the industrial conception.

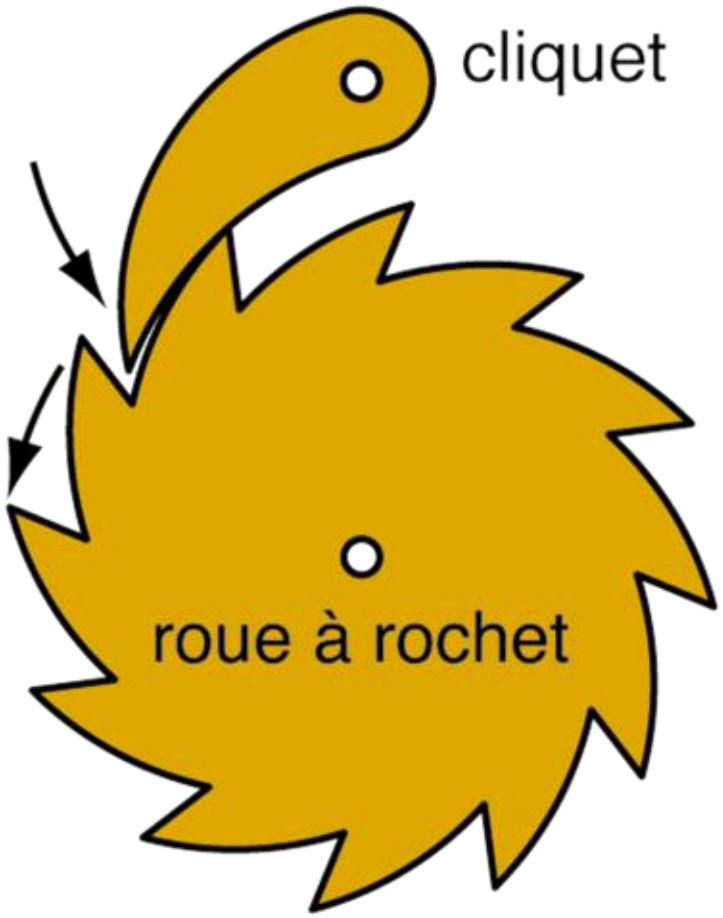
Locking system

- Strange as it may sound, I decided to look at gardening tools to come up with a new locking system for the speculum.
- So I took a ratchet gear locking system from secateurs.



Locking system

- To understand this locking system, I bought a similar product to test it in hand.
- This one works with a ratchet wheel that locks it in one position when it hits the pawl.
- Such a system would not be feasible for the speculum, unless you create several anchor points where the pawl could lock in several positions rather than just one. The video on the right allows you to see how the system works and to better analyse the problem.



Locking system

- One can therefore imagine a similar system on the side of the speculum to obtain more than a dozen blocking positions.
- However, as I mentioned before after several discussions with gynaecologists. Choosing exactly where to block the speculum allows better utilization for clinicians but also avoids discomfort for patients by keeping the speculum more open than necessary with a screw-nut type of locking system.
- This is why, even if the screw-nut system may seem more archaic, I think it is the most relevant because it meets both clinical and patient needs.

Transparent product

- Then comes the problem or rather the need for a transparent product. This requires a material that meets four clinician's needs:
- 1. Bio-compatible: is suitable for all medical applications requiring biocompatibility of contact with skin and tissue, or indirect contact with blood for a limited time
- 2. Sterilisable: does not show significant loss of mechanical properties up to 1000 sterilisation cycles.
- 3. Recyclable: allows waste to be transformed into raw material ready for use.
- 4. Transparent: can be seen through by light

Transparent product

- However, it should be borne in mind that the choice of material will also impact on the needs of the patients which are
- 1. To be more comfortable: To have a less hard material than plastique uses
- 2. To be less cold: To have a material that conducts less heat (lower heat transfer coefficient than the 316 stainless steel used, i.e. 17 W/m°C)

Transparent product

- The list of plastics that can be used in the medical field is not extensive. Therefore, I have listed those used in order to choose which one would allow to produce a transparent speculum, according to the clinicians and patients needs.
- PEEK (Polyetheretherketone)
- PPSU (Polyphenylsulfone)
- POM-C (Nylacast Polyacetal)
- PP (Polypropylene)
- PE (Polyethylene)
- PS (Polystyrene)
- Silicone
- TPE (Thermoplastic Elastomer Materials) → TPS , TPV, TPC, TPO, TPU, TPA
- PVC (Polyvinyl chloride)

Material ranking

- In order to make the most informed choice possible, I have decided to base my judgement on six criteria. Each one is defined by a particular factor.

- Biocompatible: Does the body accept contact with the material in a tolerable way?
- Sterilizable: Can the product be sterilized with an autoclave system (i.e. pressurized with water at 135°C) without affecting its properties? → water absorption as a percentage in a 24-hour cycle
- Recyclable: Can the product be 100% recycled?
- Transparency: Can the product be obtained in a transparent form?
- Hardness: What is the hardness of the material in shore D?
- Thermal conductivity: What is the thermal conductivity in W/m/K?

Material ranking

Material	Bio-compatible	Sterilizable	Recyclable	Transparency	Hardness	Thermal conductivity
PEEK	+++	0,3	Yes	+++	85 D	0,27
PPSU	+++	0,2	Yes	+++	70 D	0,25
POM-C	+++	0,1	Yes	+	80D	0,39
PP	++	0,02	Yes	+	65D	0,44
PE	+++	0,04	Yes	+++	75D	0,4

Material ranking

Material	Bio-compatible	Sterilizable	Recyclable	Transparency	Hardness	Thermal conductivity
PC	Yes	0,4	Yes	+++	80 D	0,21
Silicone	Yes	0,05	+ not infini	+	45 D	1,3
TPE	yes	0,3	Yes	++	85	5,3
PVC	Yes	0,2	Yes	+++	75 D	0,19
PTFE	Yes	0,7%	Yes	++	65 D	0,25

Material ranking

- The values shown in these two tables are average values obtained from the literature.
- Of course, each of the factors must be taken into account but also observed in relation to the other characteristics. This means that even if a material is much better in terms of thermal transmittance for example, it must still perform well in the other factors.
- That is why I have created a ranking with the help of the two previous tables, giving a score from 1 to 5 for each factor based on the data obtained.
- Thus, I can choose the material with the highest score, i.e. the material with the highest average characteristics for each of the factors which are all very important for both clients: the patient and the clinician.

Material ranking

Material	Bio-compatible	Sterilizable	Recyclable	Transparency	Hardness	Thermal conductivity
PEEK	5	3	5	5	1	5
PPSU	5	4	5	5	4	5
POM-C	5	4	5	5	2	4
PP	3	5	5	5	4	4
PE	5	5	5	5	3	4

Material ranking

Material	Bio-compatible	Sterilizable	Recyclable	Transparency	Hardness	Thermal conductivity
PC	5	2	5	5	2	5
Silicone	5	5	3	2	5	2
TPE	4	3	5	3	1	1
PVC	3	4	5	5	3	3
PTFE	5	1	5	3	4	1

Material ranking

Material	PPSU	PE	PP	POM-C	PEEK	PC	PVC	Silicone	PTFE	TPE
Result	28	27	26	25	24	24	23	22	19	17

After analysing the results, it can be seen that three materials are particularly close in terms of performance: PPSU, PE and PP.

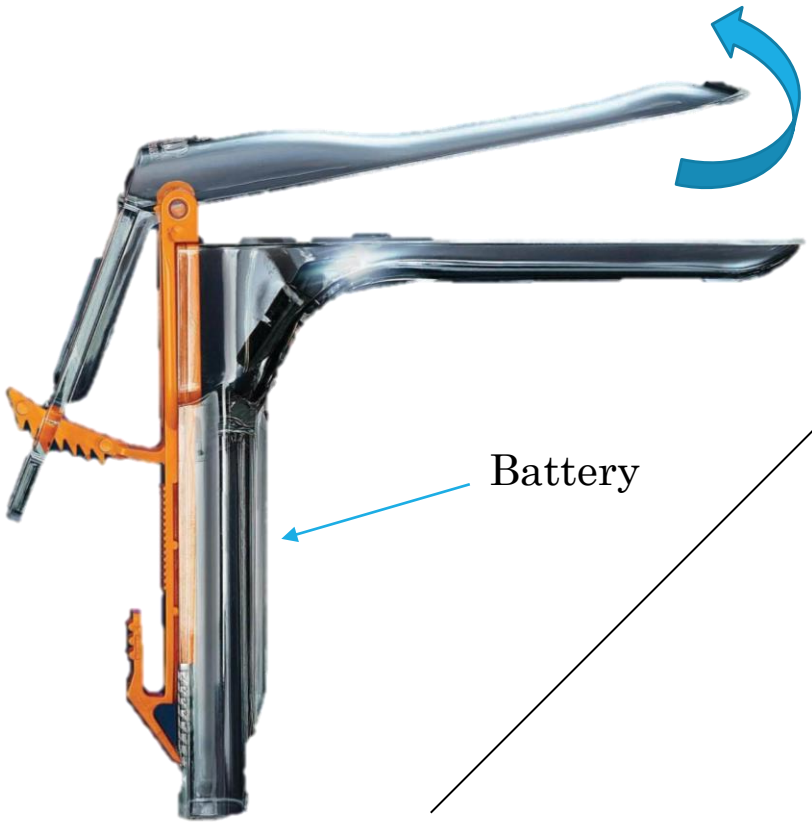
I therefore chose PPSU to produce the new transparent speculum in plastic injection.

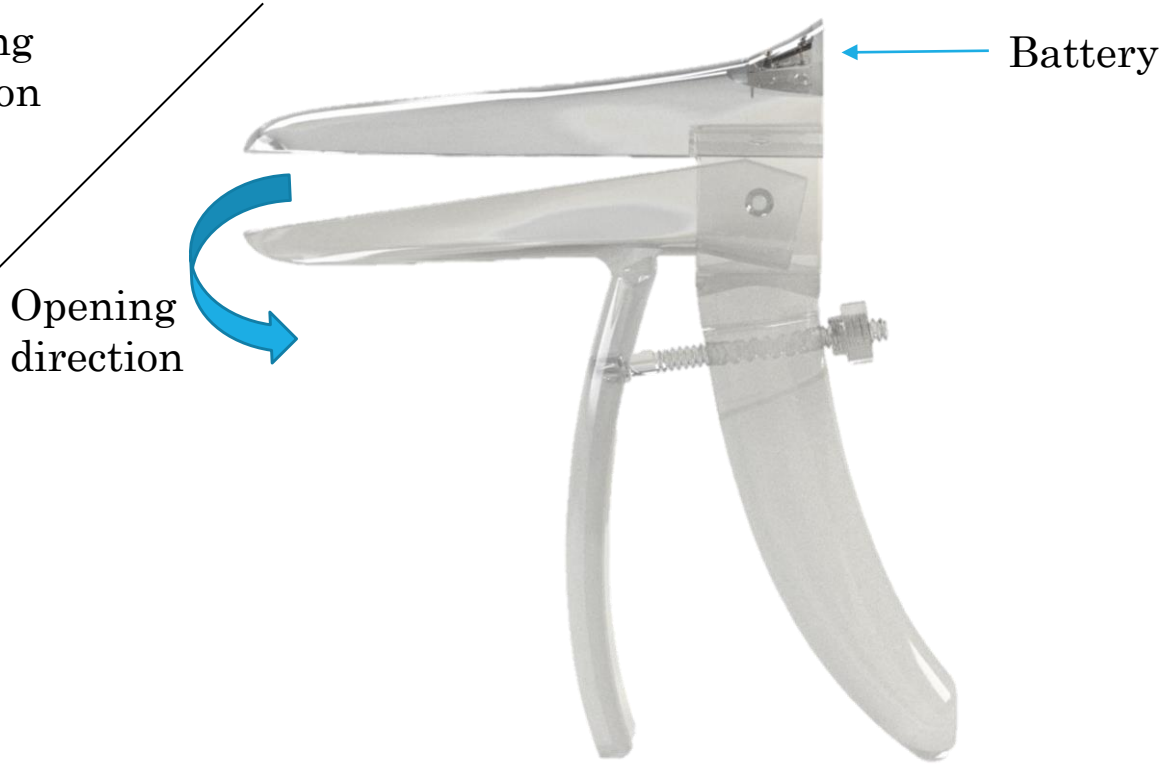
Lighting system

- To solve the problem of luminosity, I first looked at what already exists in the field to take the good ideas, but also to avoid some of the pitfalls.
- So, I found three products that correspond to the needs of clinicians. The first two images show you two speculums, each with an integrated lighting system. Both are from OBP.
- The last image shows a product that can be easily clipped onto a speculum to provide illumination.
- Looking at these two different techniques, I realise that the position of the battery can only be in the top of the speculum in my case and not in the handle because of the opening system I have chosen.

Lighting system

- To understand the challenge I face, I have produced a simple diagram to show how OBP's product is designed and how I produce mine.





Lighting system

- I have to place the light and the battery in the upper part of the speculum so as not to create cables that would circulate from the handle to the lamp located at the top of the speculum.
- This choice is not related to feasibility but by the complexity that would increase the price of the product. By simplifying my design as much as possible, I am able to reduce the cost of manufacturing my product and make it accessible to hospitals and gynaecological centres.
- However, this does not only have advantages. On the contrary, it means that I have to design a block where the lamp, battery and switch will reside in a smaller space.

Choosing the light

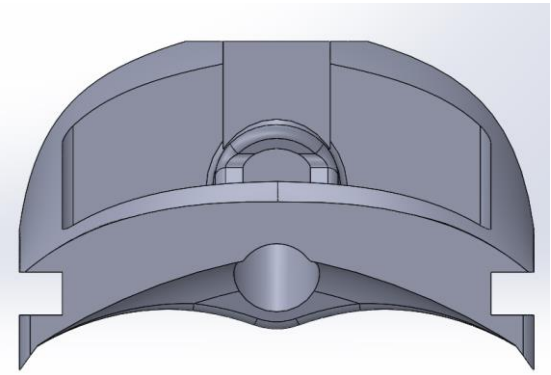
- Choisir la LED n'est pas une mince affaire. Tout d'abord, j'ai décidé de focaliser mes recherches sur le site RS-Online qui possède des milliers de références en matière de LED. Dedans, j'ai une gamme extrêmement large, voir même trop large. On se perd rapidement parmi toutes les références avec toutes les caractéristiques qui les différencients:
- -Tension nominale
- -Couleur du flux
- -Intensité
- -Taille de la lampe
- -Angle de vue
- -Etc …

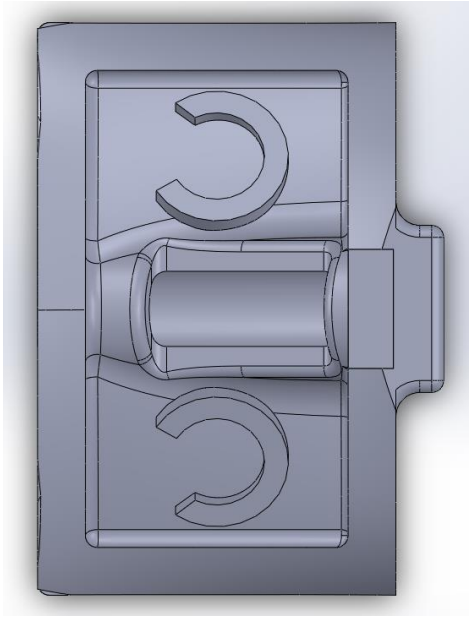
Choosing the light

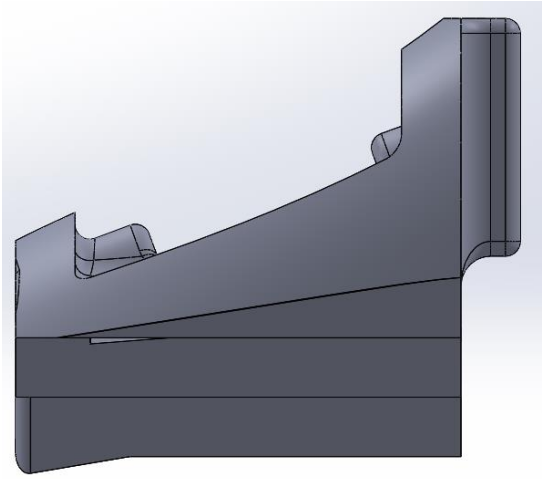
- Pour réussir à faire un choix judicieux, il faut d'abord savoir qu'est-ce qui va alimenter le système. C'est d'ailleurs pour cette raison entre autre que je dois revoir le choix de ma première LED.
- Ce qui paraît evident à première vue est que la batterie doit être au format d'une pile. Evitant ainsi d'augmenter le prix du produit en rajoutant un système de chargeur et en simplifiant l'étape en demandant simplement à l'utilisateur de changer les piles. Il peut d'ailleurs faire le choix d'utiliser des piles rechargeables dans un soucis écologique.
- Avec la photo ci-dessous, vous pouvez déjà observer le nombre de pile qui existe sur le marché.

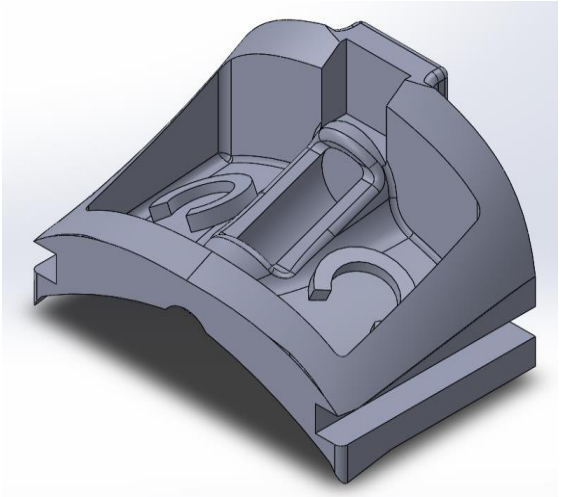
Choosing the light

- Néanmoins, celle qui nous intéresse dans le cas present, ce sont les piles plates.
- Elles disposent certes d'un stockage en énergie plus faible. Mais ells ont pour ells une taille réduite qui permet d'en disposer plusieurs dans un seul boitier.
- On peut ensuite les brancher en série pour additionner leur voltage et ainsi alimenter une lampe qui fournira une lumière plus importante.









Lighting system

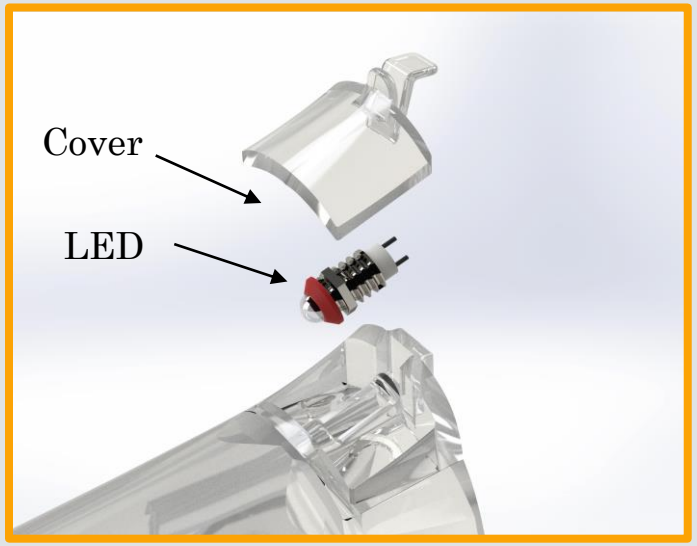
- The first design I produced was focused on what was to be in this "habitat", i.e.:
- -A battery
- -A lamp
- -A push button
- -An electronic card
- I chose button cells to serve as a battery to save space. A LED for lamp from RS because it can work with a low voltage of 2V as provided by the button cells.
- Finally, for the push button and the electronic board, I decide to leave it aside while I answer another problem. What design should be produced to make this small housing accessible and sterilizable?

Lighting system

The first design I developed is based on a space at the top of the speculum closed by a clip-on lid.

The technique is rather simple, but it allows the clinician to quickly change the batteries for example without the need for a screwdriver or other tools.

To create sufficient space, I have increased the size of the speculum slightly, but this part is not the part that is in contact with the patient. This will not create any discomfort for her. Also, the clinician's working space is not reduced.



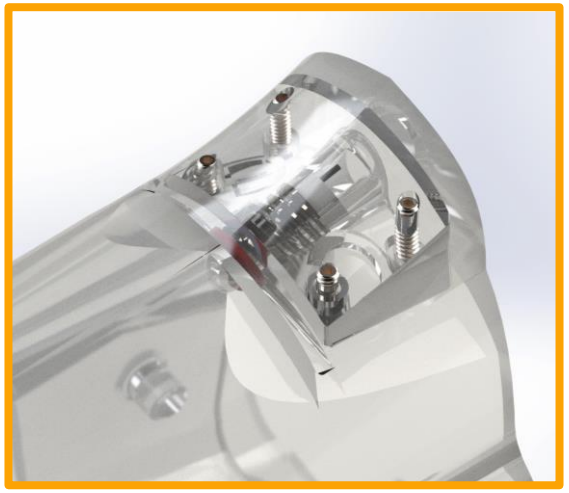
Lighting system

In this new image you can see an exploded view of the product to understand more precisely how the product is designed.

As you can see, the LED is simply clipped into the holder and not screwed or glued.

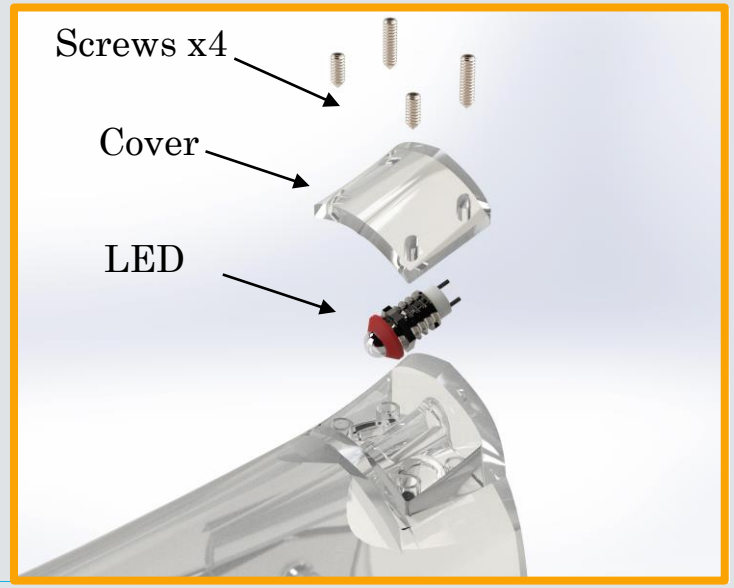
This allows for easy replacement in case of malfunction.

However, you have to keep in mind the presence of cables, the two batteries in the casing and that are not yet physically present in the design.



Lighting system

- My second design is the use of screws this time to close the lid.
- This has the advantage of producing an airtight seal which is mandatory in the case of a boil-in-the-wool sterilisation as I envisage.
- However, it has the disadvantage of requiring clinicians to have a screwdriver in case of battery failure.
- This is an impossible problem to solve in the case of a surgical operation where everything has to be sterilised.
- So this solution is also flawed and I have to make a choice.



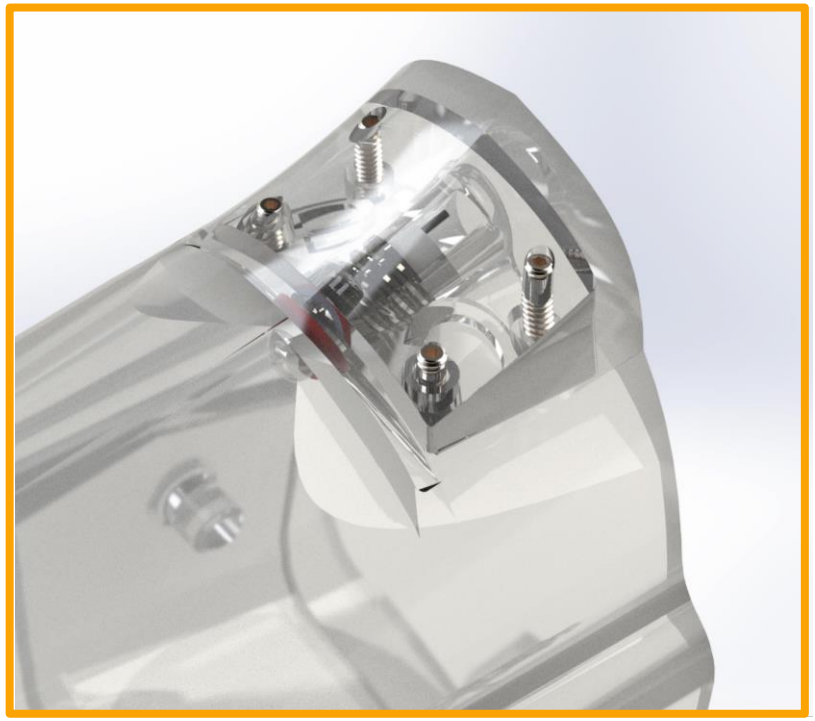
Lighting system

- This exploded view shows the design of this second design.
- It consists of four M1.6 flat-head socket headless screws of lengths 6 and 8 mm.
- Like the previous design, the LED is recessed in a half cylinder for easy replacement.

LIGHTING

FIRST SOLUTION

Finally, for this first system, I obtain an autonomy of 7 hours of use.
This can also be translated into 84 patient visits, taking into account that one visit requires an average of 5 minutes of speculum procedure.
This means a battery change every 8 days.



White LED =LE-KP-4

Battery = LR621

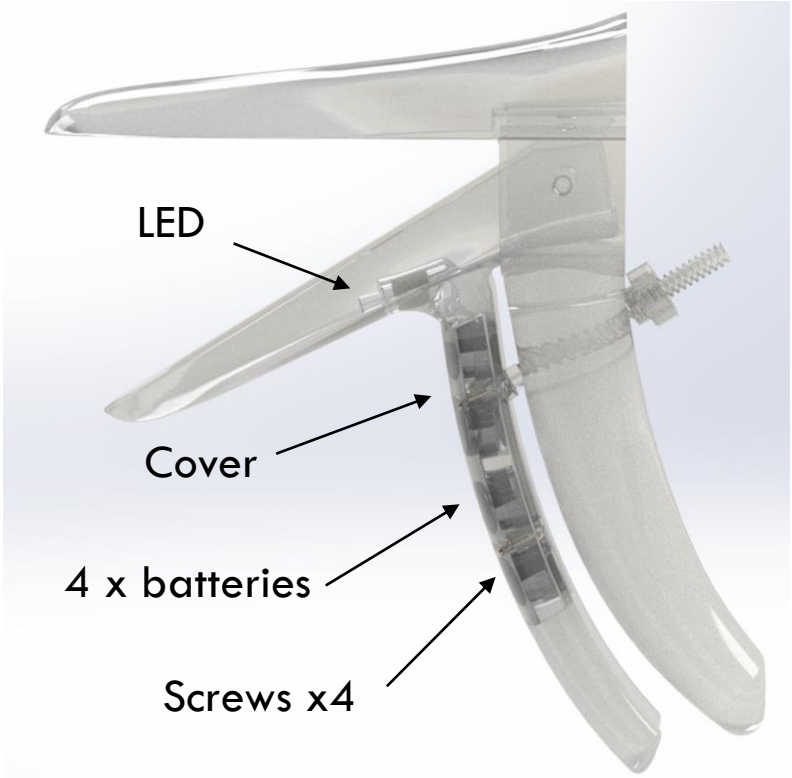
Lighting system

- After thinking about it, I decided to think about a second version of the system to analyse if it was possible to make the product capable of a better autonomy.
- Putting the battery in the handle is to be ruled out as it then requires wiring along the handle to the top of the spout, thus complicating the product and also the mould as this kind of product is made in plastic injection.
- So I decided to put the batteries in the trigger. This way I am able to put 4 batteries instead of 2, larger size and therefore with a better storage capacity.

LIGHTING

FIRST SOLUTION

This second version allows for a much better autonomy while using an LED with a better lighting potential.
The autonomy increases from 7 to 16 hours.
This is equivalent to observing 192 patients or 17 days before having to change the batteries.



White LED =LE-BP-6

Battery : LR44

Transparent walls

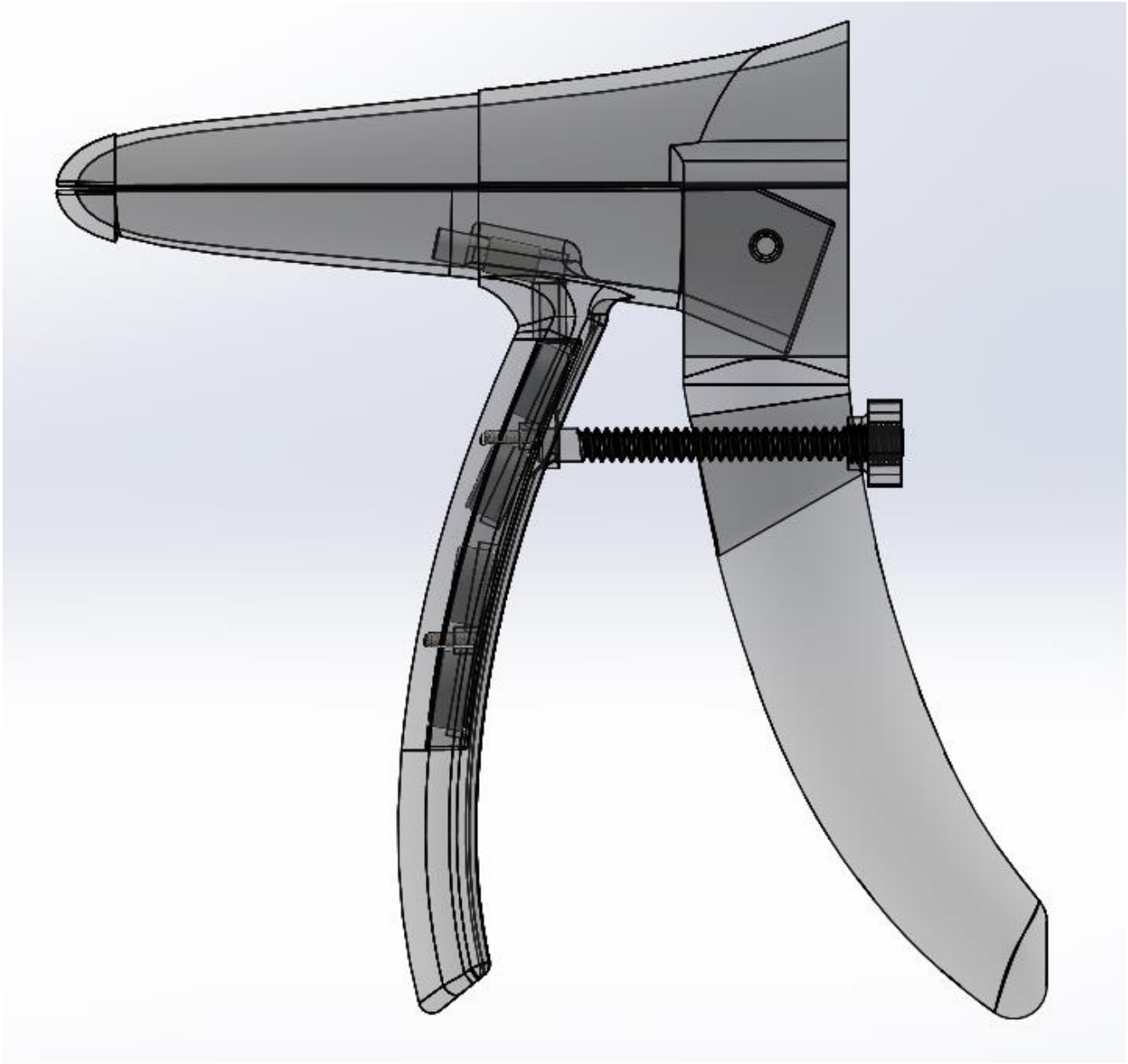
- One of the last and most sensitive points of the design forced me to imagine the whole process of using the speculum to make sure that I was providing the best solution to this need.
- Thinking about it in depth, I realised that the biggest problem I have to face is sterilization. Indeed, if we take elements from my tests, the most efficient transparent wall system is the one using a condom. This is made of PU and does not withstand temperatures above 90°C. Since the sterilization process raises the product to 135°C, the transparent walls would not last even one sterilization cycle.
- They must therefore be disposed of after use like a condom. The simplest design for this is a PU cylinder with an opening on both sides.
- This allows the clinician to access the cervix for e.g. a smear test.

Transparent walls

- The idea behind this solution is to have a product that is easy to use for clinicians while keeping costs low.
- To achieve this, the design of the transparent wall is designed to be a simple PU cylinder with a diameter of 47 mm and a thickness of 0.5 mm.

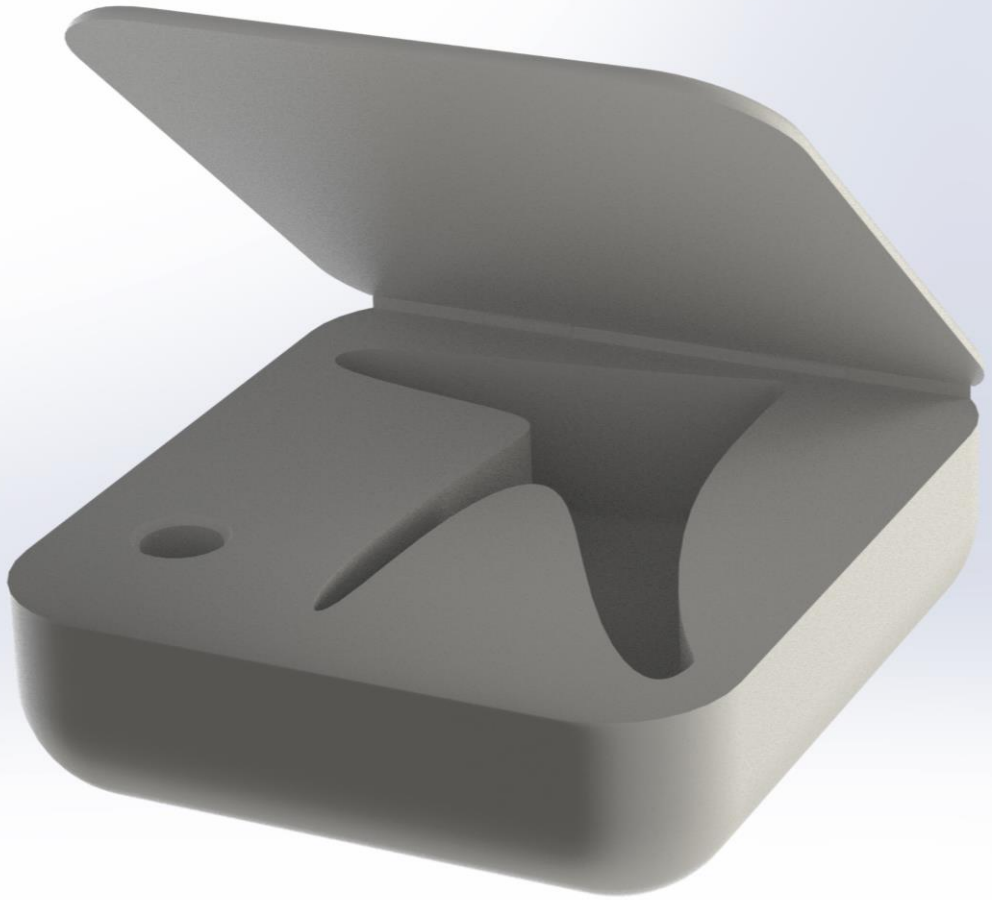
Transparent walls

- In order to make the transparent wall fit better and be less intrusive for the patient. I decided to make a hole all around the beak of the speculum where the transparent cylinder should be.
- This way, it fits into this recess so as not to create any extra thickness that might be uncomfortable for the patient.



Transparent walls

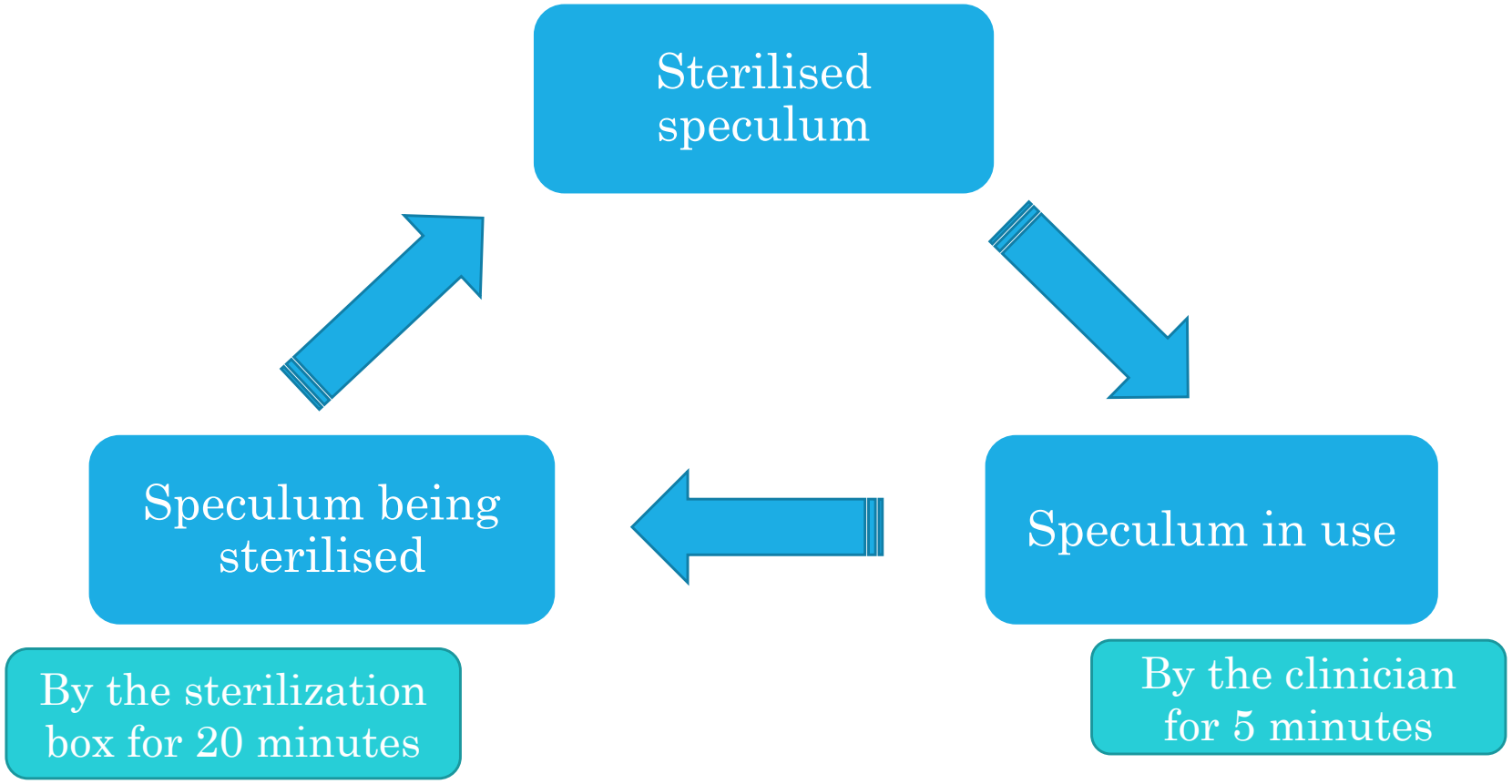
- This side view allows a better view of the bored part.
- A thickness of 0.5 mm has been removed, which is the thickness of the transparent wall.



Sterilization box

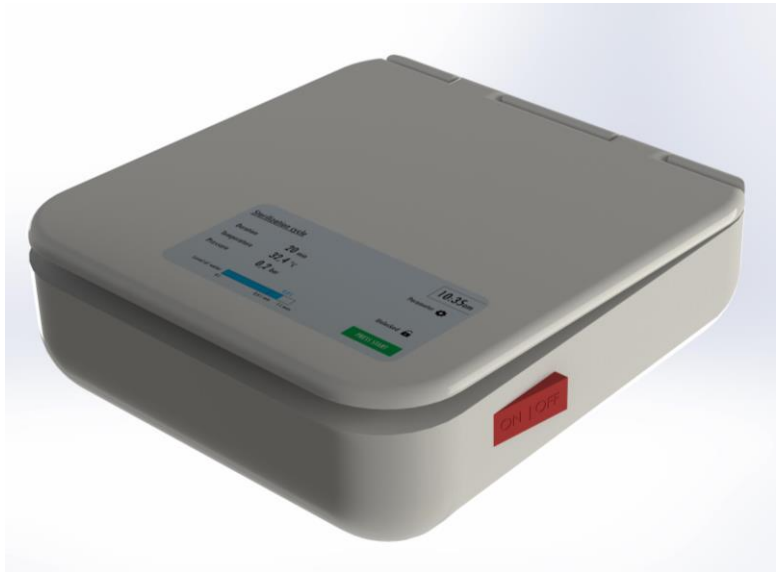
- It is the last point to define and it is not the least because its role is capital.
- Every day it will have to be used more than ten times, that is why it must work perfectly. In addition, it must provide the clinician with an easy to use and fast operating support.

Cycle d'utilisation



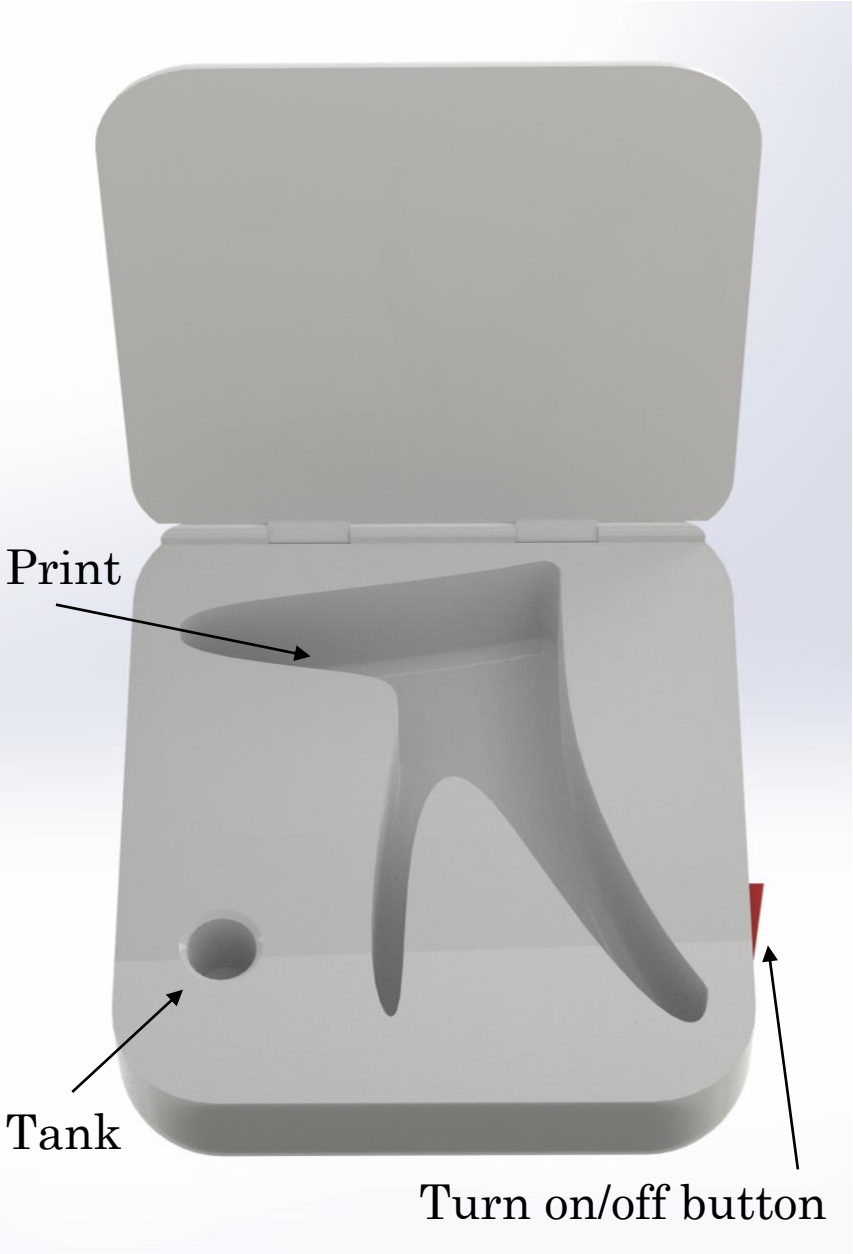
Cycle of use

- This cycle of use requires each clinician to have his own sterilisation box in his office.
- In addition, he should have at least three speculums at his disposal so that he always has one in advance that is already sterilised while another is being sterilised.
- Of course, since there are several sizes of speculum, the clinician should have six speculums at his disposal.



Design of the sterilisation box

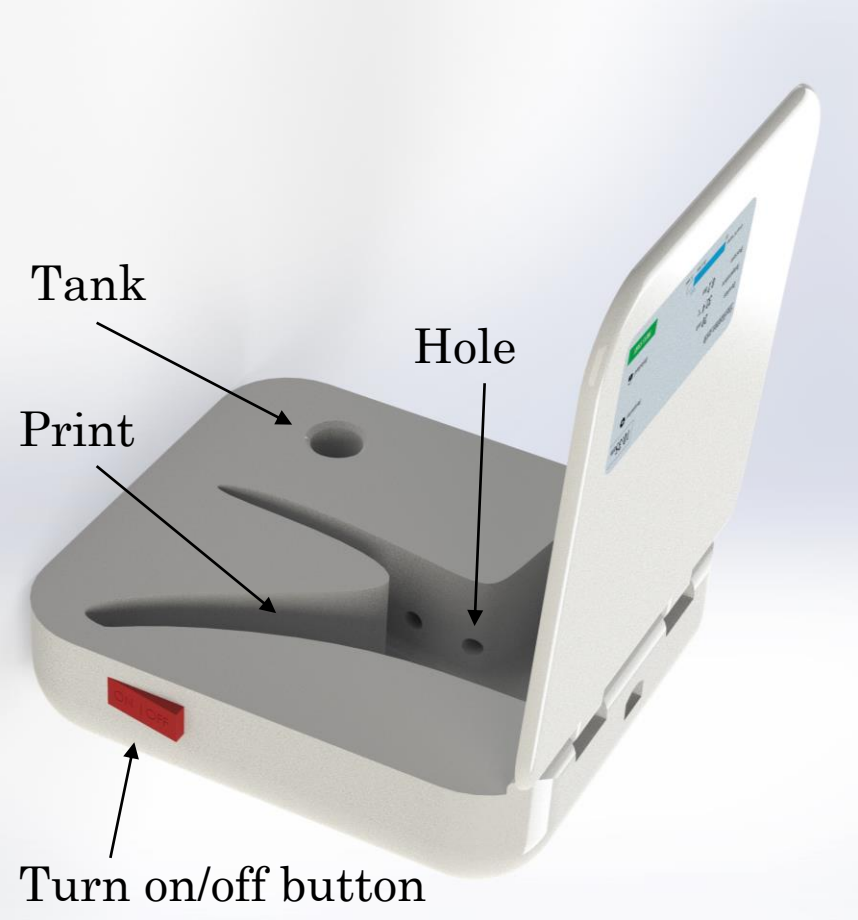
- The design of the sterilisation box is based on three foundations:
- 1. An imprint: to place the speculum
- 2. A reservoir: to hold the sterile water
- 3. A touch screen: to start the system and observe the operating parameters.



Design of the sterilisation box

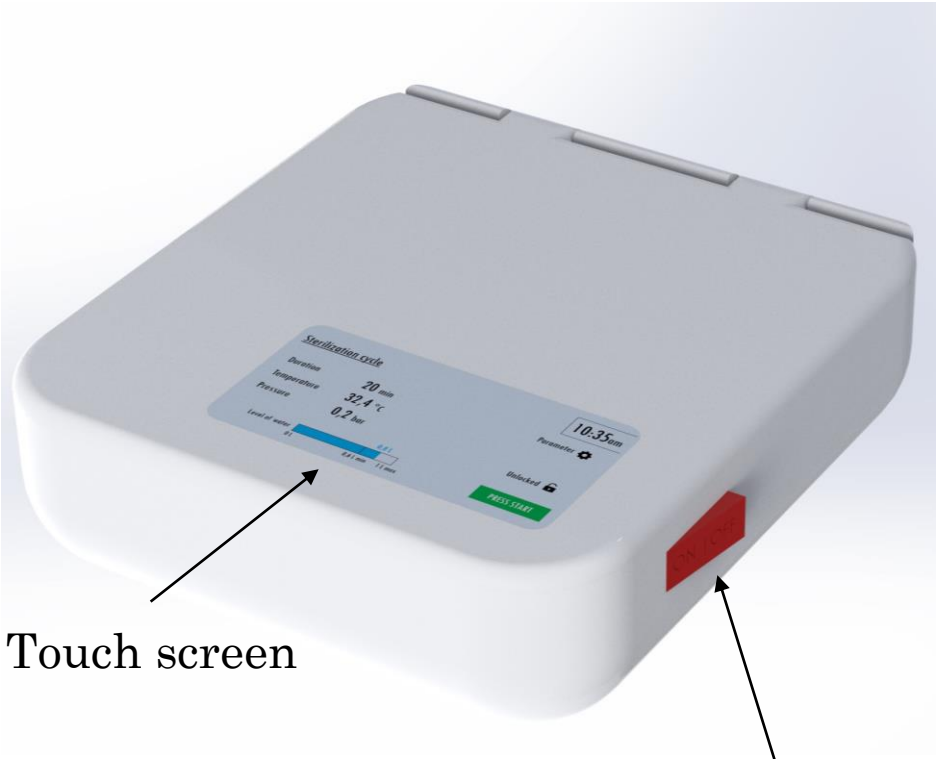
- As for the footprint of the speculum, it is based on the largest size so that the three different models can be placed in it.
- Then there is a tank with a capacity of 1 litre.
- It is very important that the system is watertight because when the box is in operation, the water is pressurised to reach a temperature of 135°C so that the sterilisation is effective.

Design of the sterilisation box

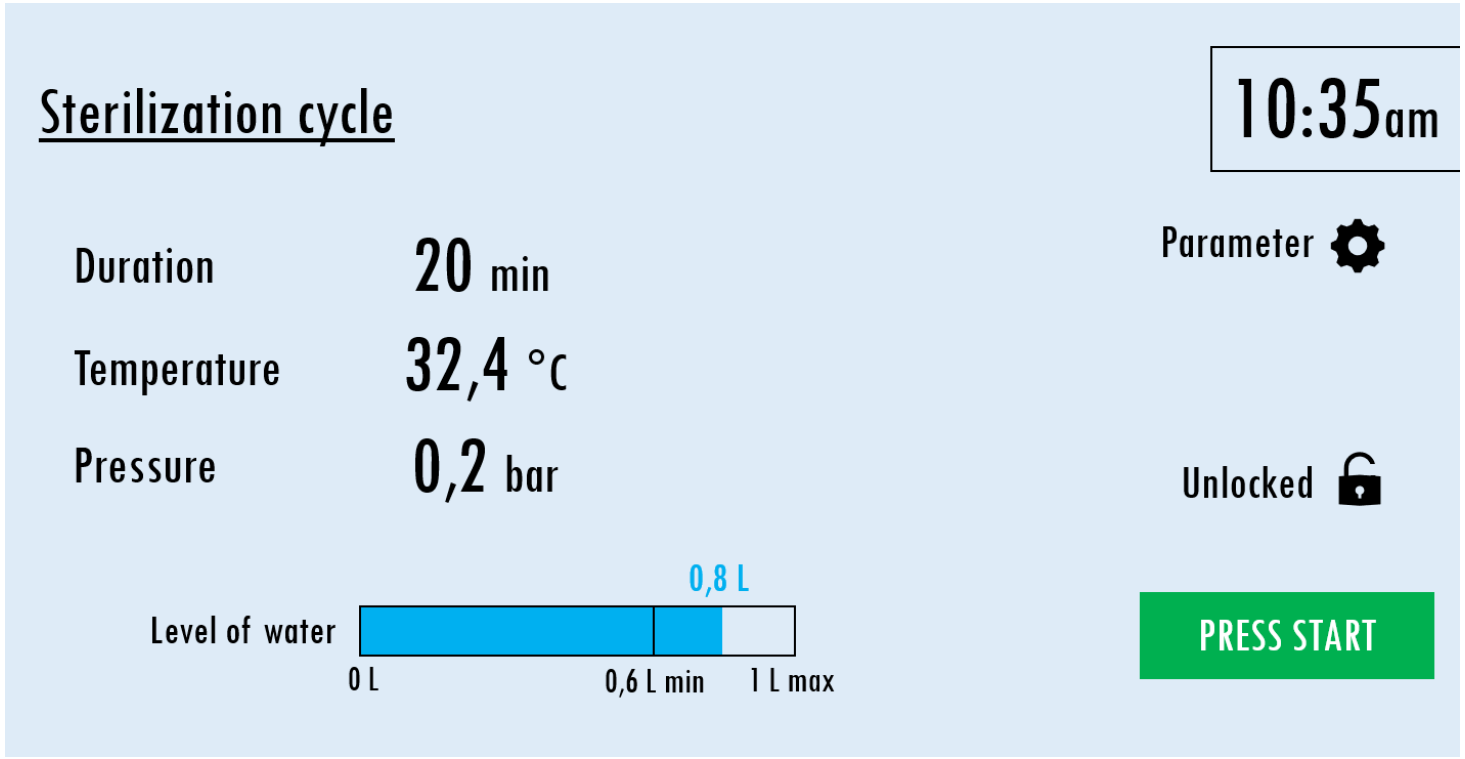


- The circulation of water for sterilization is done through holes in the impression.
- These are close to the bottom of the impression so that all the water is sucked out at the end of each 20 minute sterilisation.
- The bottom of the impression is curved towards the reservoir for easy emptying.

Design of the sterilisation box



- In addition to the system presented above, a system to control the device is needed.
- For this, I chose a touch screen to facilitate its use. This one lights up as soon as the red switch is turned to the ON position.



Design of the sterilisation box

- The interface provides access to two options: The parameters and the start button.
- The parameters allow the user to change the temperature, time and pressure during the sterilisation process.
- The start button is permanently displayed and is only replaced by a stop button when a sterilization is initiated.
- It is there to interrupt a procedure that has been started by accident or whose parameters have been wrongly chosen.

Story board

- This part is dedicated to transform sketching into maps.

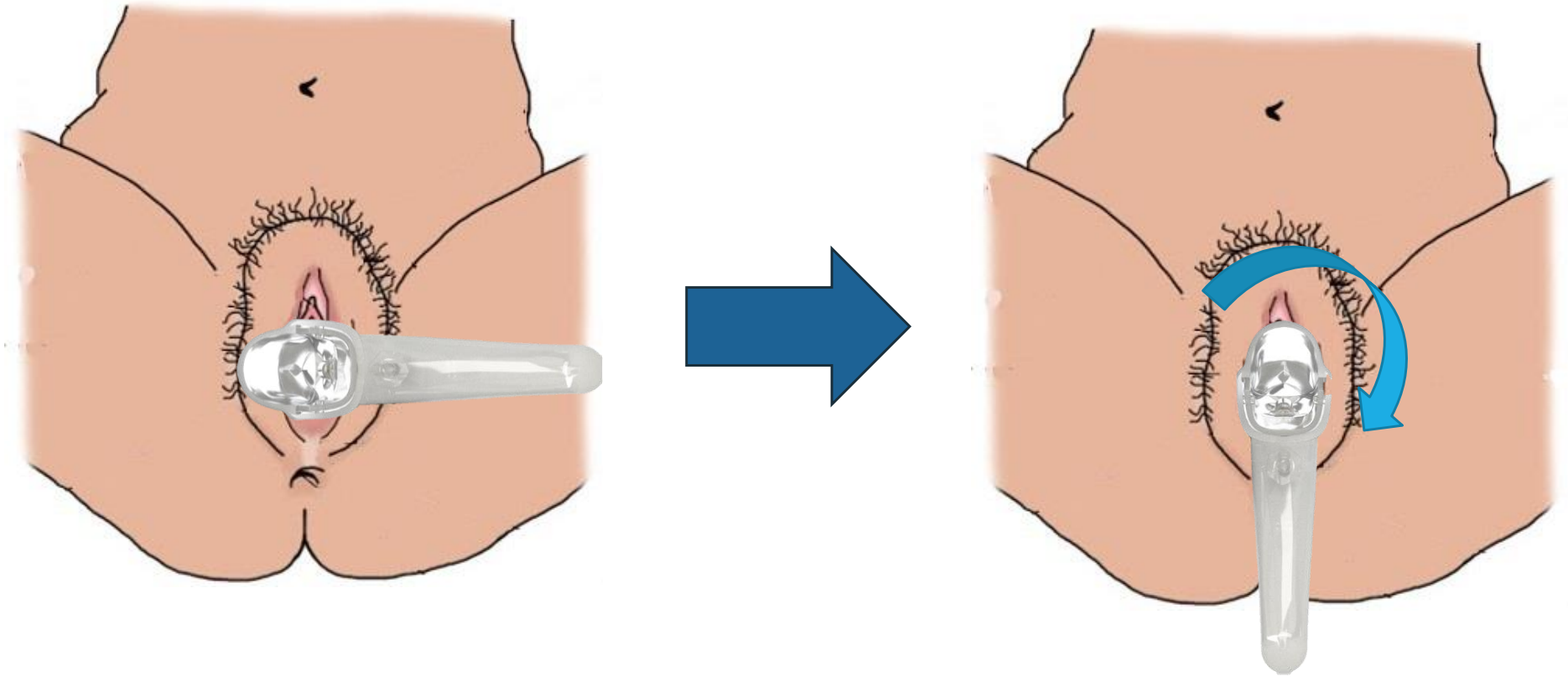
Storyboard

- The first step in the use of this new product is to explain it to the patient. This is a key point that was highlighted by the online questionnaire and interviews.
- Patients ask for the procedure to be explained to them before undergoing it.
- The clinician takes care to explain how he will use the speculum, but also why he is doing it. For example, they may say that they want to look at the cervix for signs of cancer.

Storyboard

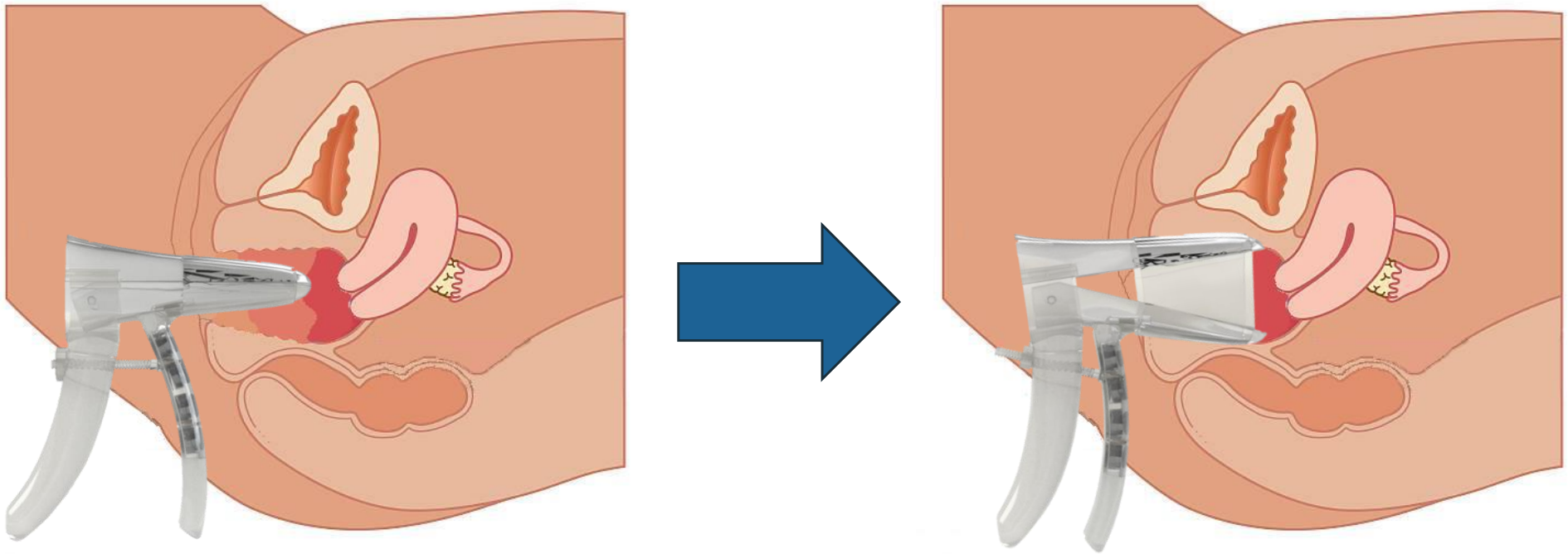
- The clinician must then slip a PU cylinder around the speculum's mouthpiece. The clinician is guided by the borehole to position it correctly.

Storyboard



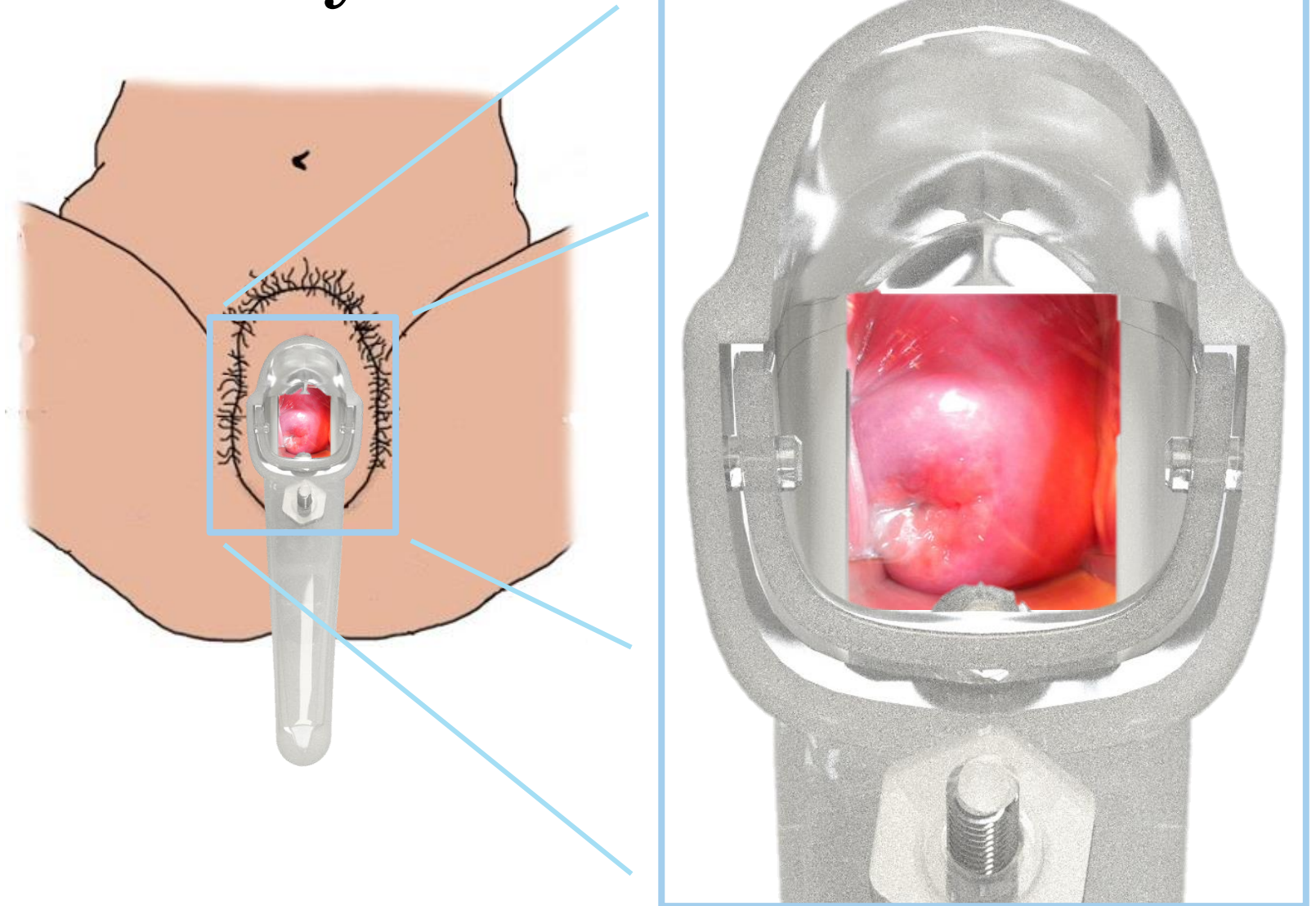
- For insertion, the clinician takes care to penetrate the patient using the speculum horizontally and not vertically to make it less uncomfortable for the patient.

Storyboard



- Once the speculum is in position, it can be opened to observe the cervix and the walls of the vagina.

Storyboard

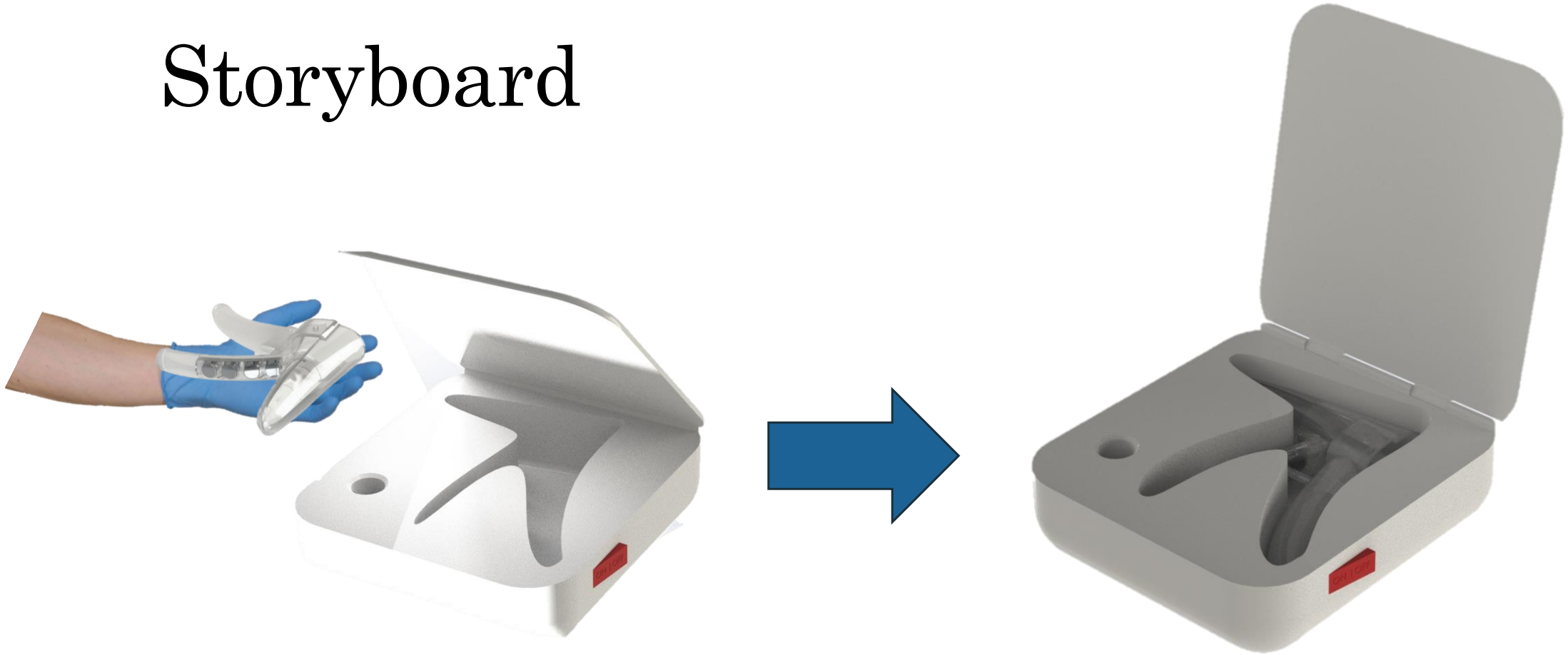


- The open speculum then allows the clinician to observe the cervix to ensure that there are no signs of cancer or other disease or infection.
- Once the observation is complete, the speculum is slowly removed by twisting it again as it was done for insertion.

Storyboard

- Once the observation is complete, the clinician can dispose of the clear cylinder in a medical waste bin in the room.

Storyboard

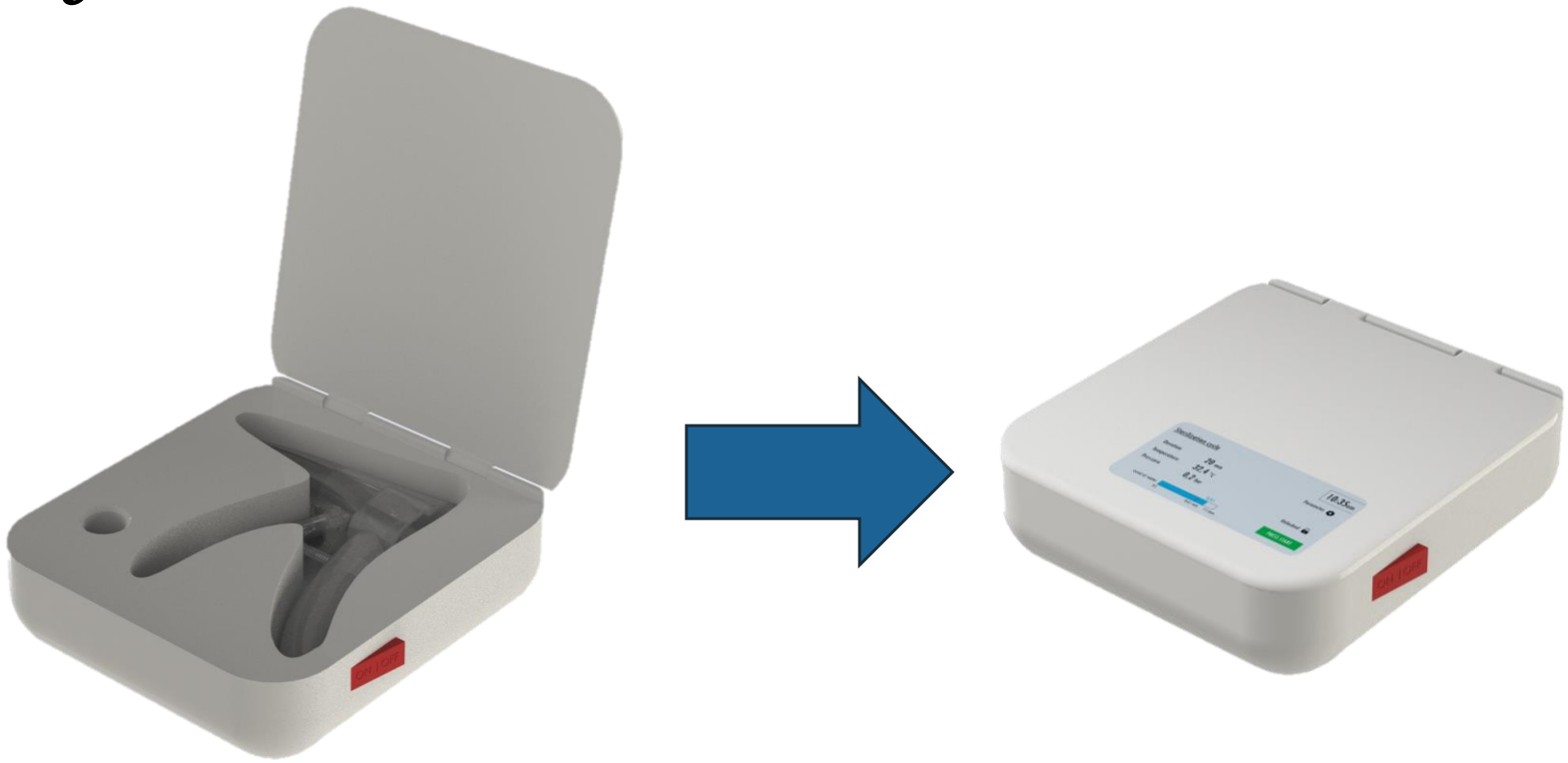


- Once the speculum has been used, it must be sterilised. To do this, the clinician places it in the sterilisation box. The sterilisation box has a special recess where the speculum, whatever its size, can rest.

Storyboard

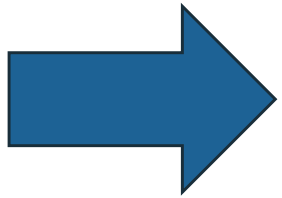
- Once the speculum has been deposited, the clinician should pour sterile water into the container through the hole provided.
- A small indicator along the neck of the container allows the clinician to see if enough fluid has been poured in or if further filling is required.

Storyboard



- The clinician then closes the box, taking care to do so until the safety catch engages to make the seal. This produces a clicking sound when it is done correctly. To prevent the possibility of a poor seal, the system cannot be engaged without the safety catch being engaged.

Storyboard



- The clinician then checks that the machine is switched on using the switch on the side and can then choose his or her settings or directly start the sterilisation procedure which will take 20 minutes. Once the sterilisation is complete, the clinician can use the speculum again and put on another one for sterilisation.

Manufacturing

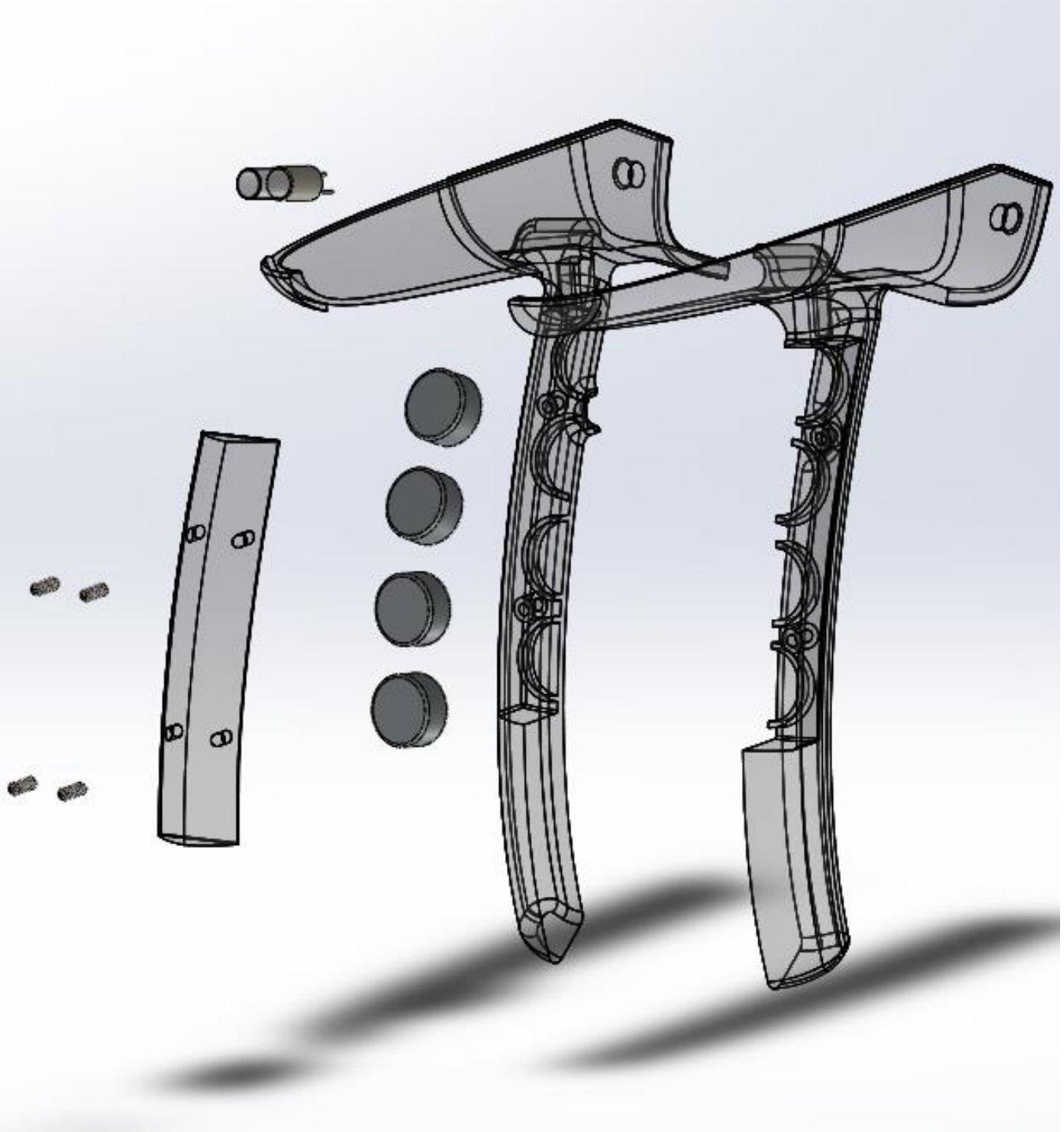
- This part is dedicated to explanation of how to produce the future speculum

Manufcaturing strategy

- When you look at the product as it is, it is easy to see that it would be difficult to manufacture.
- The awkward shapes and the interlocking of the parts forced me to think of a solution to allow plastic injection without creating too complex moulds.
- Indeed, most plastic artists will tell you that anything can be produced, it just depends on the price you are willing to pay.
- Wanting absolutely a low cost product, I decided to divide my parts in several parts.

Manufcaturing strategy

- So I divided the handle into two symmetrical parts which are attached to each other with screws, but also with glue.
- Screws alone would not make the product strong enough. That's why I suggest using glue on the spout to ensure the product is strong enough.



Manufacturing strategy

- For the trigger, the strategy is much the same.
- Divide it into several symmetrical parts but without a fixing point this time.
- The product would simply be glued with an industrial glue such as Loctite.

Manufacturing strategy

- This is what the finished product looks like.
- This is how it is laid out before each use where it is not yet covered with the PU cylinder to prevent prolapse of the vaginal walls for overweight patients.

Market place

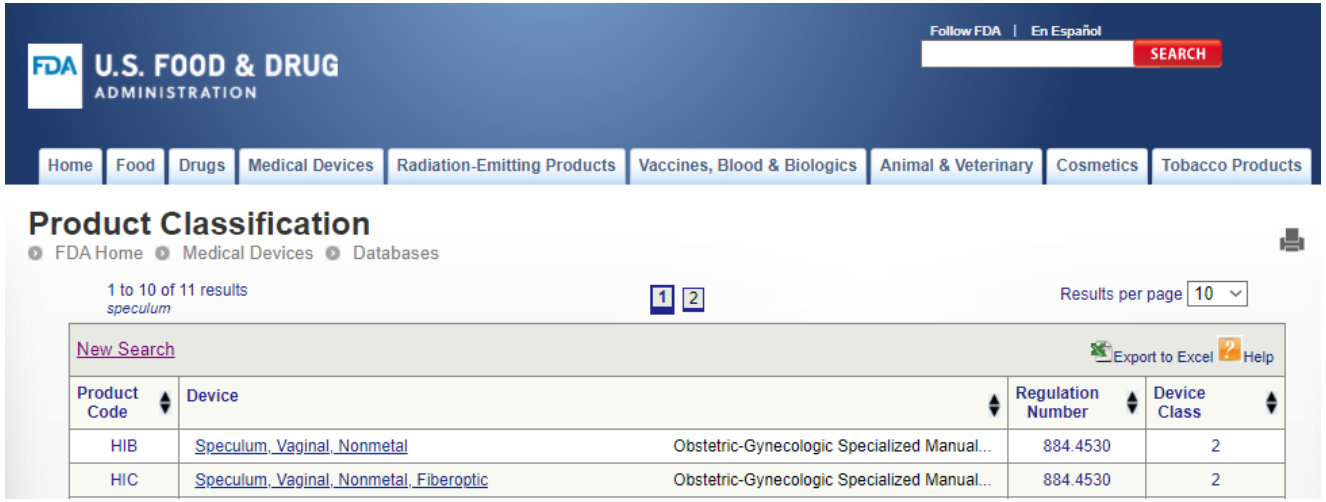
- This part is dedicated to explain how the product may and can be introduce on the market of medical devices.

How to introduce the product?

- Bringing a product to market is far from being a trivial operation. On the contrary, it is the critical step that can lead a product to disappear or on the contrary to revolutionize its genre.
- However, before imagining any marketing or advertising strategy, it is important to bear in mind that it is a medical product.
- This means that it must be approved before it can be marketed.
- The laws vary from country to country, so let's take an example from a large market such as the United States. In order to sell equipment with the medical designation, it must be validated by the FDA. The role of the Food and Drug Administration (FDA) in the United States is to protect public health by allowing only safe and effective products to be marketed and by monitoring the safety of the products on an ongoing basis after they are used.
- To do this, you must undergo an audit that verifies that you comply with all the indications recommended by the FDA for the type of product you wish to market.

How to introduce the product?

- In our case, we have to look at the classification of the product according to the FDA. There are 3 categories according to the dangerousness and the type of use of the medical equipment in question.
- To be sure of the type of classification, we can simply use the FDA database. The image below is a screenshot of the database:



How to introduce the product?

- Thus, the non-metallic speculum is classified as type 2. One can then analyse the long list of prerequisites for the implementation of such a product such as a detailed risk analysis of the product, a thorough definition of the tests, etc...
- However, this kind of work is never done alone. All companies therefore call on specialists such as BSI to produce a single audit to meet the requirements to analyse all aspects of the product's life cycle, including research and development, manufacturing and quality assurance which must be in line with FDA standards.
- Only then can the product be sold to hospitals and maternity wards.

Conclusion

Conclusion

- I am proud to show a finished product that can be presented to a company for further production.
- Despite possible improvements and some missing tasks like the production of a detailed risk analysis.
- This new speculum design meets the demands of patients and clinicians. By being both more ergonomic, allowing better visibility of the cervix. While being more comfortable, warmer and less austere than the old design.
- All that is missing is a test phase and validation by a group of clinicians for this product to see the light of day and improve the daily lives of thousands of women.

Personal conclusion

- This project is really something exceptional for me in the true sense of the word. I never expected to work in such a field and even less to give myself so much to find solutions.
- It is a real discovery from the point of view of my initial preconceptions. I must admit that I did not feel legitimate to work on a product aimed exclusively at women. But after reflection and discussion with many Irish gynaecologists and surgeons, I realised my mistake. The product may be used on female patients, but it can still be designed by a man. However, they need to be involved in making the product work for them.
- That is one of the things I am very pleased of, is that I have been able to reconcile both sides. On one hand, the clinicians' desire to get a product that can treat all women, especially overweight women because the product shows weaknesses in continuing the procedures. And on the other hand, for the patients who, for the most part, experience these examinations with great stress, which can even traumatise them, thus pushing them to stop going to their gynaecologist. It was only after a dozen interviews and several dozen answers to my online questionnaire that I realised that communication problems can also play a big role in the medical field.
- Because stress problems are not only related to problems with the design of the speculum, but they are also caused by the lack of communication and information that this produces in patients. More than 75% of patients complained that the clinician had not taken the time to explain the procedure to them beforehand, and then did not bother to listen. In a society that has never been so connected with social networks and mobile phones, it is surprising that this barrier still exists between patients and clinicians.

Annex

Annex 1: Microsoft form

Feeling on the speculum

A speculum is a duck-bill-shaped device that doctors use to see inside a hollow part of your body and diagnose or treat disease. One common use of the speculum is for vaginal exams. Gynecologists use it to open the walls of the vagina and examine the vagina and cervix.

* Obligatoire

Thank you for your help, it would only take five minutes of your time

1. I declare that I have been fully briefed on the nature of this study and my role in it. I understand how the information collected will be used. I fully understand that there is no obligation on me to participate in this study and that I am free to withdraw at any time. I am also entitled to full confidentiality in terms of my participation and personal details. I declare that I am a woman between the ages of 18 and 65. I agree to participate in this survey. *

   ○ Yes

   ○ No

Annex 1: Microsoft form

2. Have you ever experienced a procedure with a speculum?

- ○ Yes
- ○ No

3. How old are you?

- ○ 18-25
- ○ 25-40
- ○ 40-55
- ○ 55-70
- ○ 70-100

4. How many times have you gone through a procedure involving a speculum?

- ○ 1 time
- ○ About 5 times
- ○ About ten times
- ○ Dozen of times
- ○ Several dozen of times

Annex 1: Microsoft form

5. At what age did you undergo a procedure involving a speculum for the first time?

- 15-25
- 25-40
- 40-55
- 55-70
- 70-100

6. What was the reason?

- Yearly inspection
- To start a prescription for a contraceptive drug
- Smear test
- To check up to investigate for symptoms
- Pregnancy
- Other
- To assess your gynecological health.
- To diagnose a medical condition

Annex 1: Microsoft form

7. If other, please describe the reason why your gynaecologist used a speculum on you

Entrez votre réponse

8. In advance to having the procedures, did you understand what it would envolved?

- Yes
- A little bit
- Not really
- No

9. Did you feel stress before the procedure?

- Yes, a little bit
- Yes, really
- No

Annex 1: Microsoft form

10. If so, what was the reason for this?

- ○ Fear of the pain
- ○ Fear of the discomfort
- ○ Fear of the embarassement

11. Were you happy about the explanations given before the procedure involving the speculum?

- ○ Yes
- ○ Not totally
- ○ No

12. Were you happy about the explanations given during the procedure invovling the speculum?

- ○ Yes
- ○ Not totally
- ○ No

Annex 1: Microsoft form

13. Did you experiences any of theses followings during the procedure?

- [ ] Discomfort
- [ ] Fear
- [ ] Cold
- [ ] Stress due to the design of the product
- [ ] Pain
- [ ] None
- [ ] Other

14. If other, please describe.

Entrez votre réponse

15. What improvements would you like to see made to the speculum?

- [ ] Have a product less stressfull
- [ ] Have a product more confortable
- [ ] Have a product less cold
- [ ] Have a softer material

Annex 1: Microsoft form

16. Please ellaborate if you have any other comments about what you would like the speculum to be.

Entrez votre réponse

17. If it was possible, would you like to conduct minor procedures like smear test at home by yourself?

- Yes
- No
- Maybe

18. Have you other comments to add?

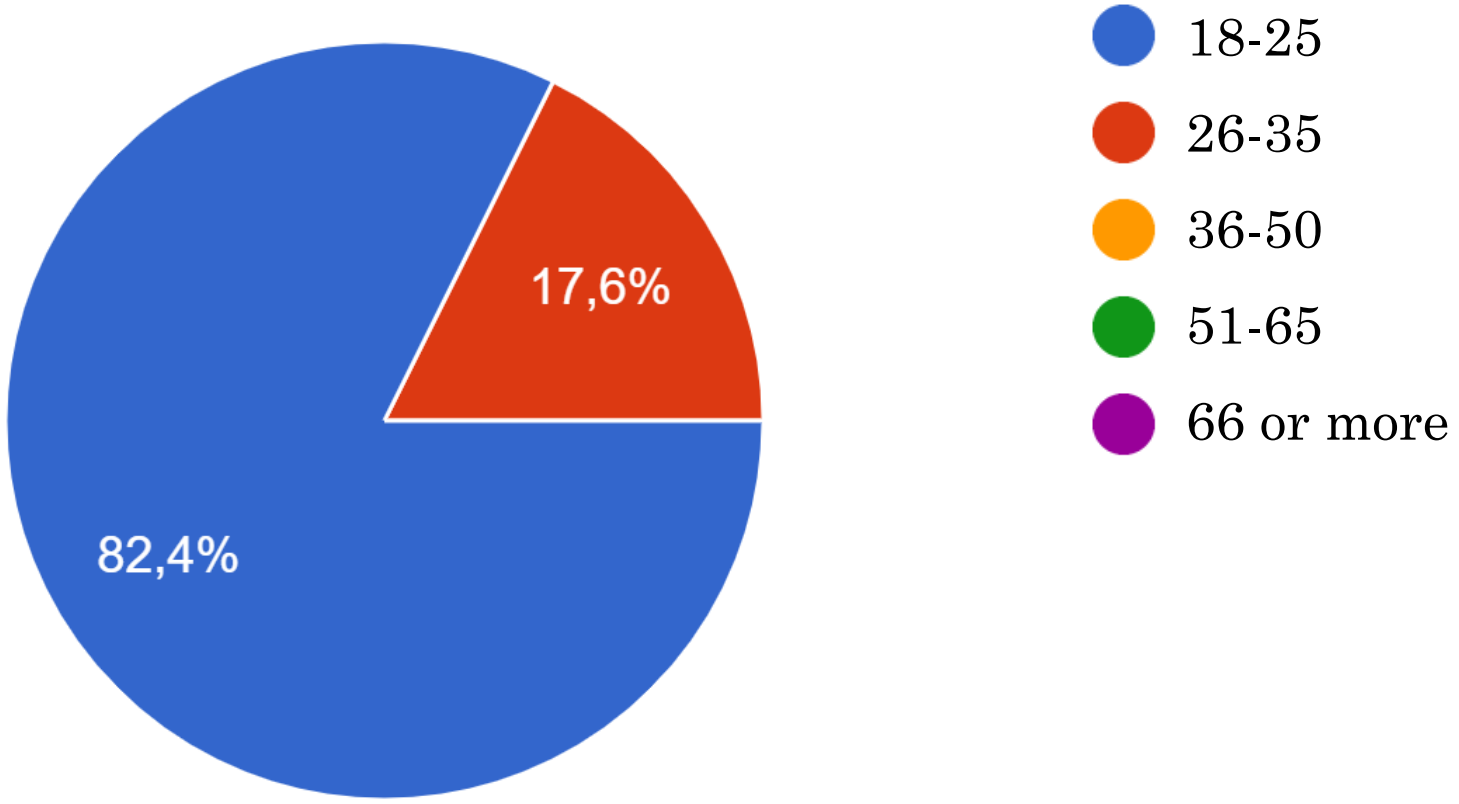
Entrez votre réponse

19. How did you find this questionnaire?

☆ ☆ ☆ ☆ ☆

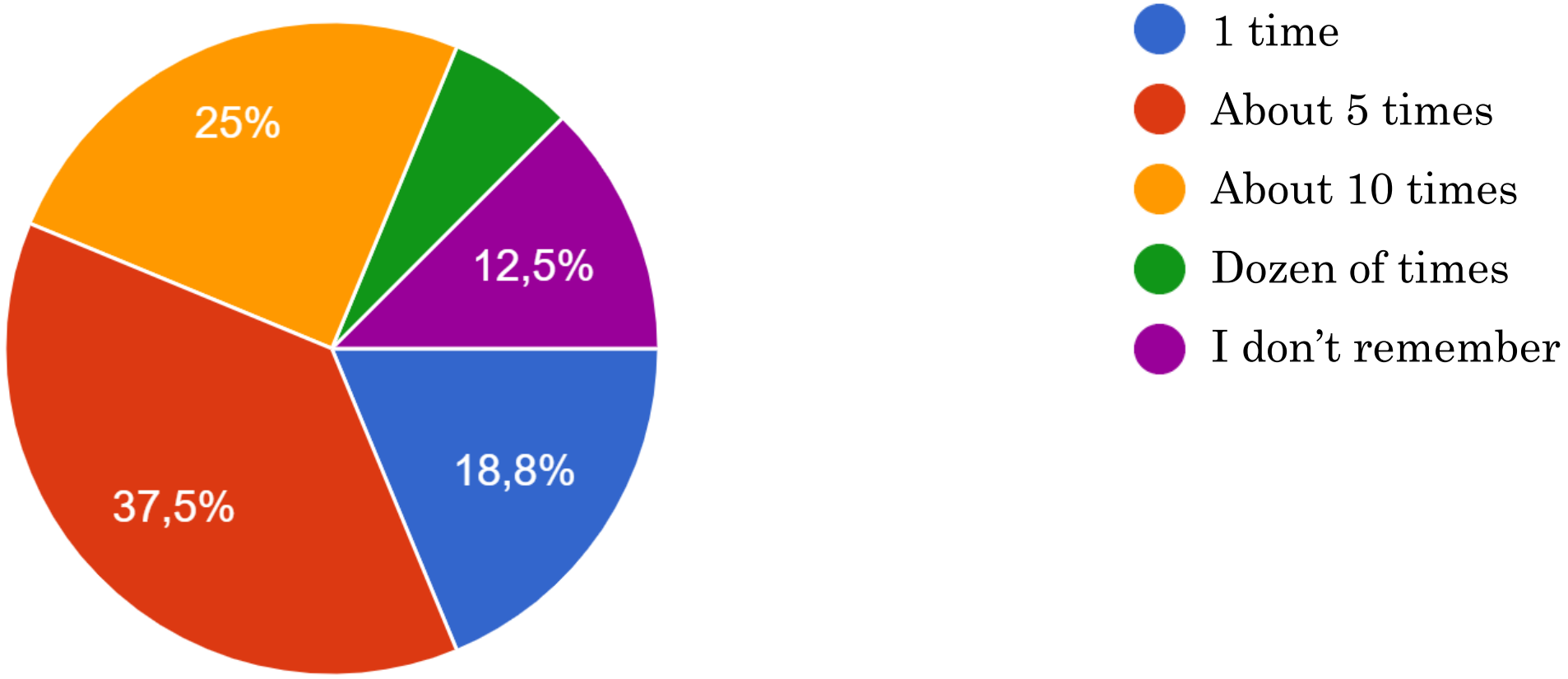
Annex 2: Result of the online form

- What is your age?



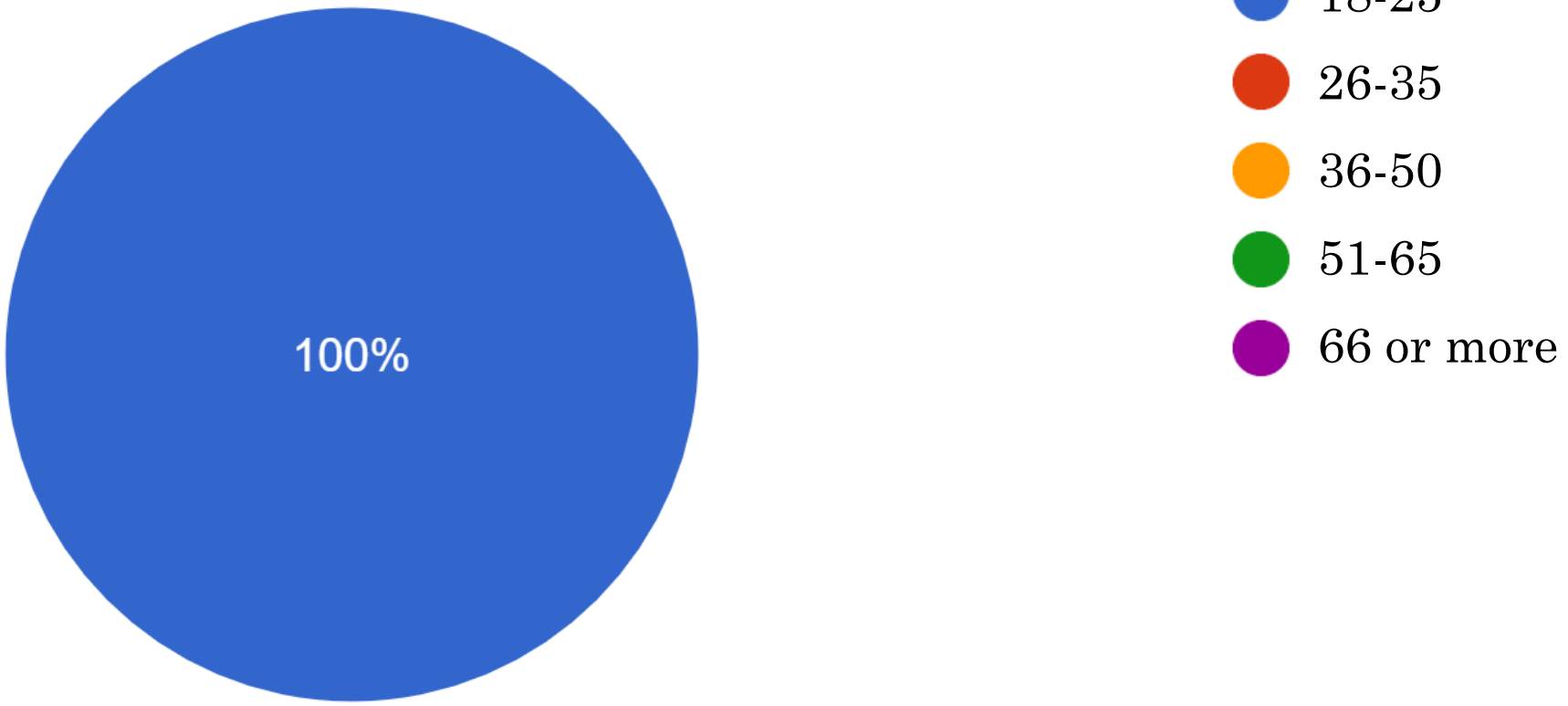
Annex 2: Result of the online form

- How many times have you gone through a procedure involving a speculum?



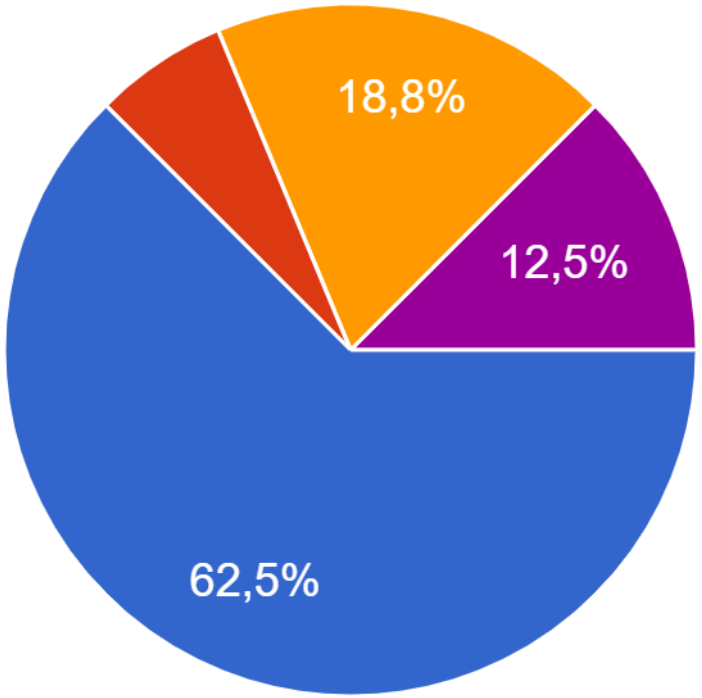
Annex 2: Result of the online form

At what age did you undergo a procedure involving a speculum for the first time?



Annex 2: Result of the online form

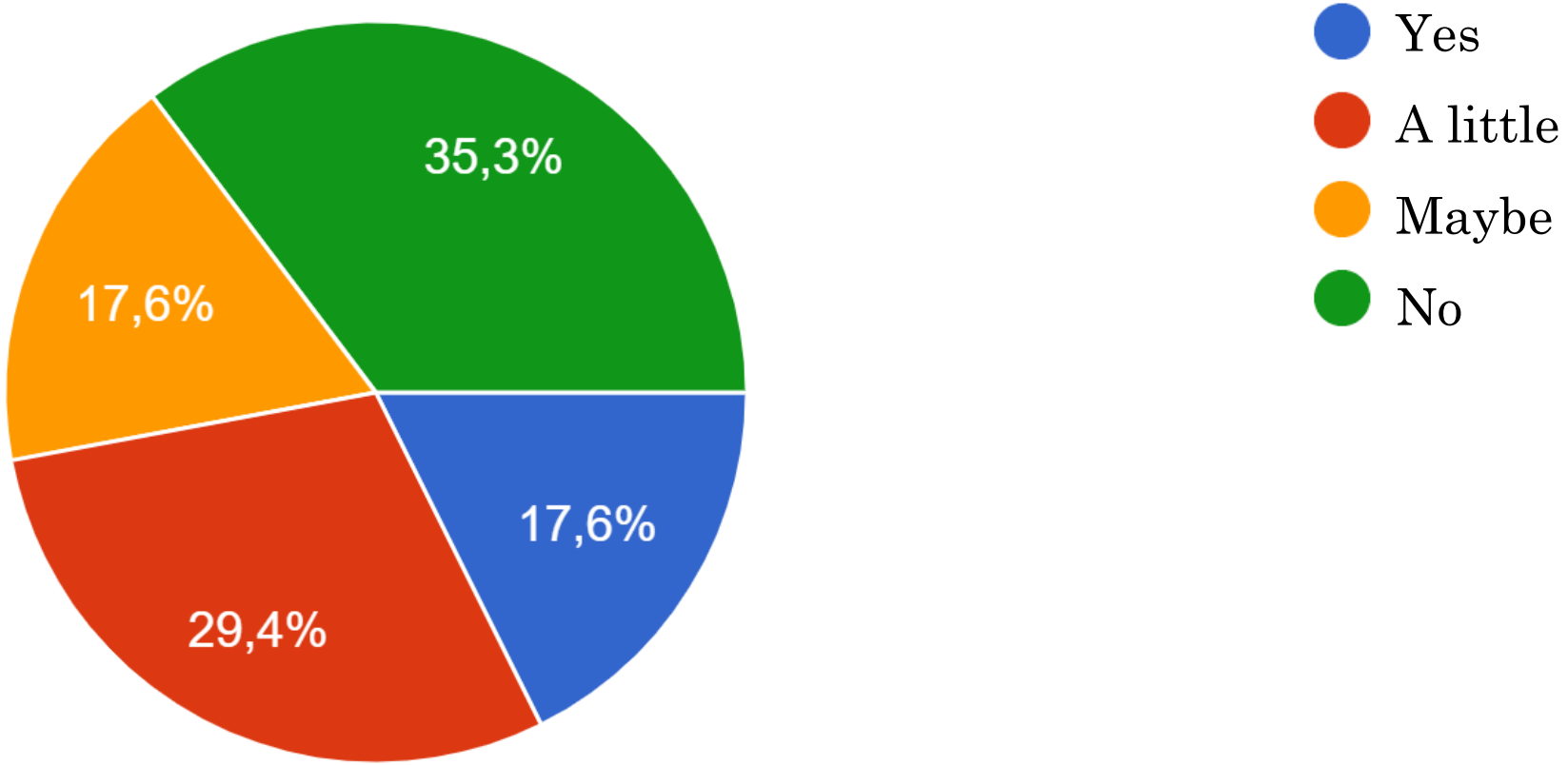
- What was the reason?



- Yearly inspection
- To start a prescription for a contraceptive drug
- Smear test
- To check up to investigate for symptoms
- Pregnancy
- Other
- To assess your gynaecological health
- To diagnose a medical condition

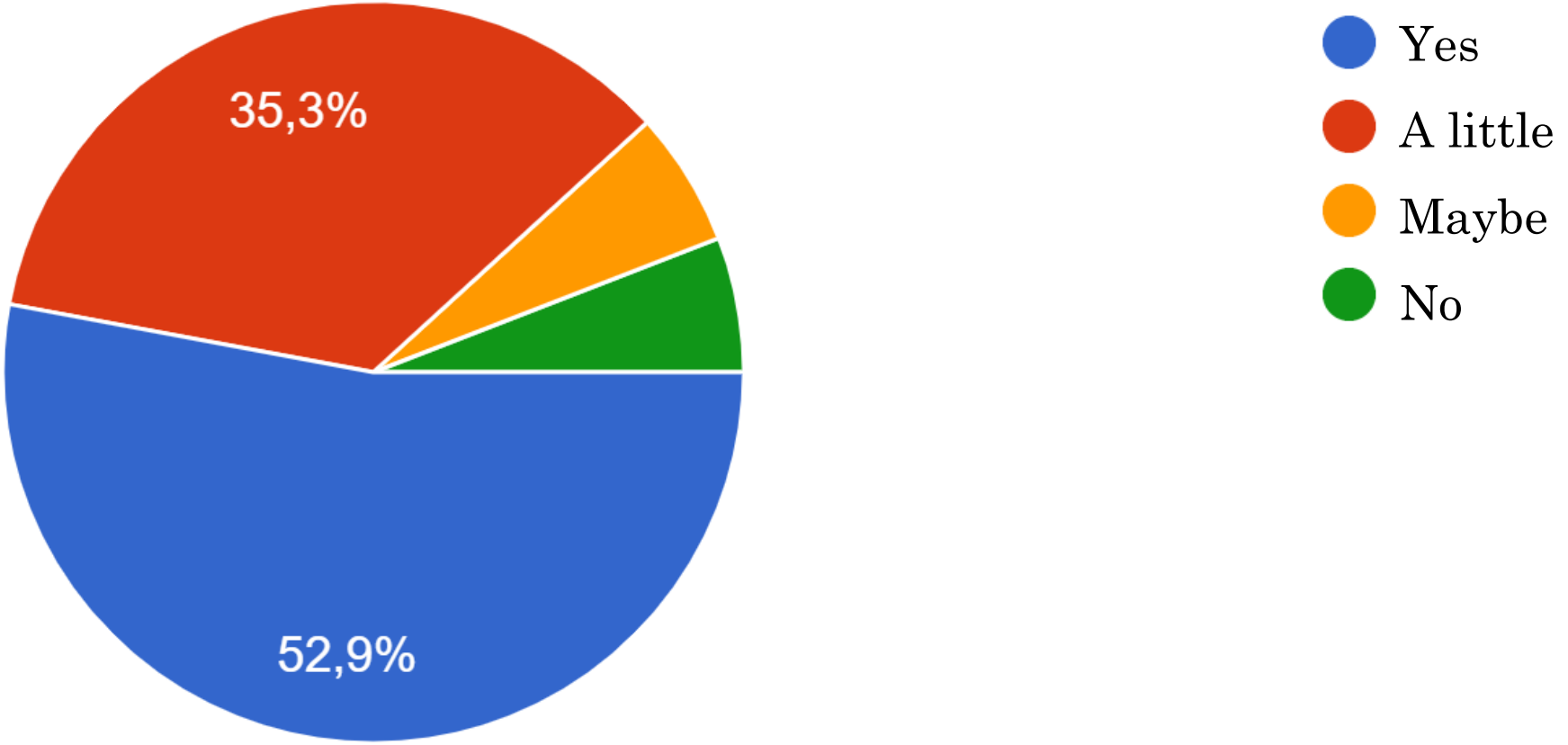
Annex 2: Result of the online form

- In advance to having the procedures, did you understand what it would envolved?



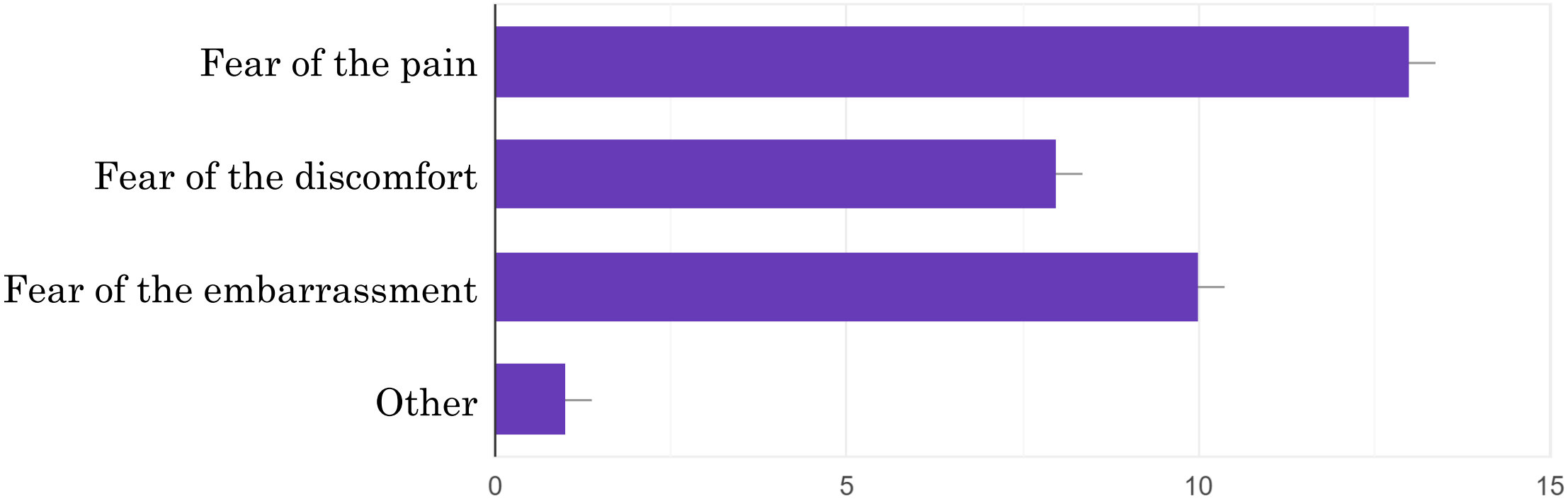
Annex 2: Result of the online form

- Did you feel stress before the procedure?



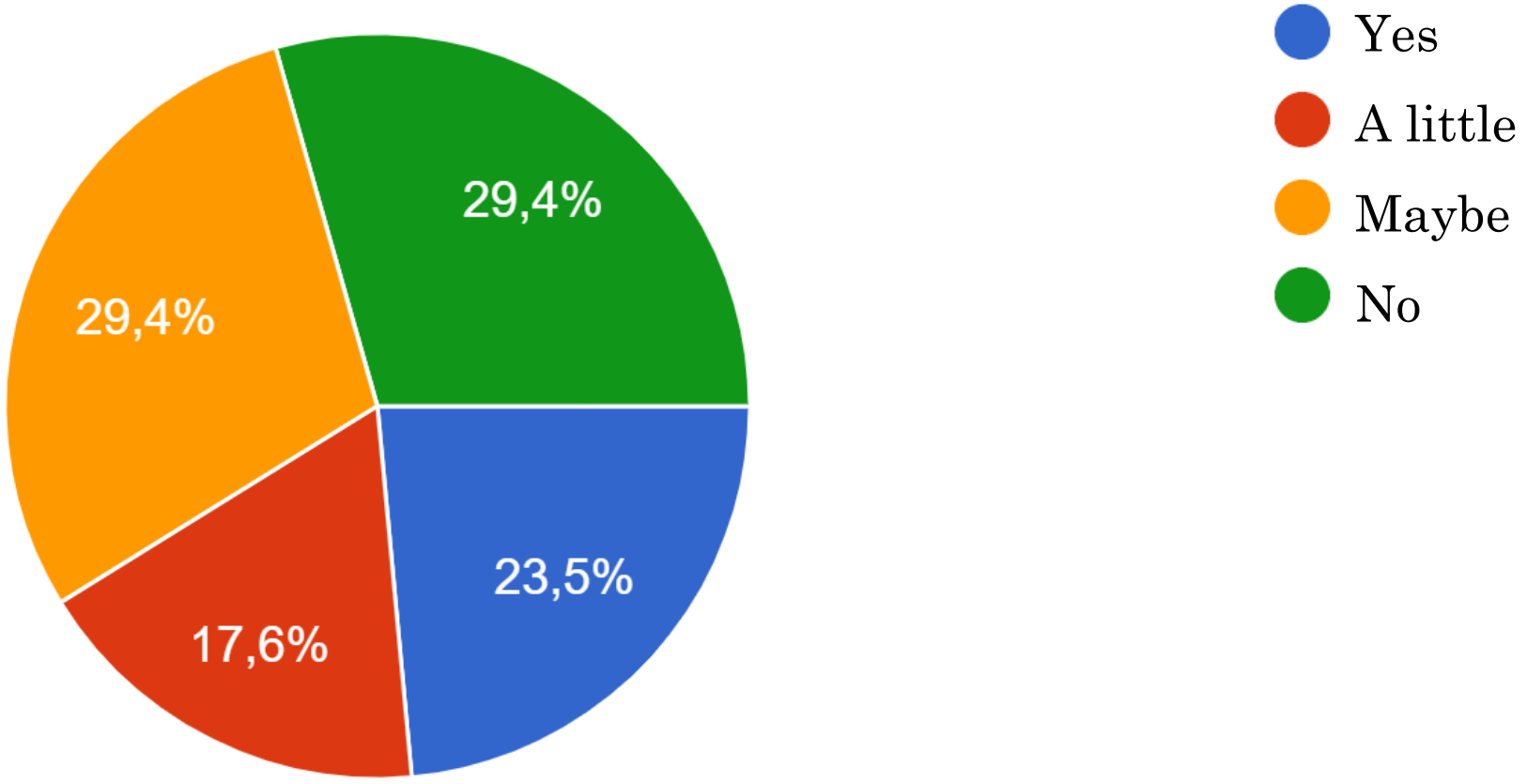
Annex 2: Result of the online form

- If so, what was the reason for this?



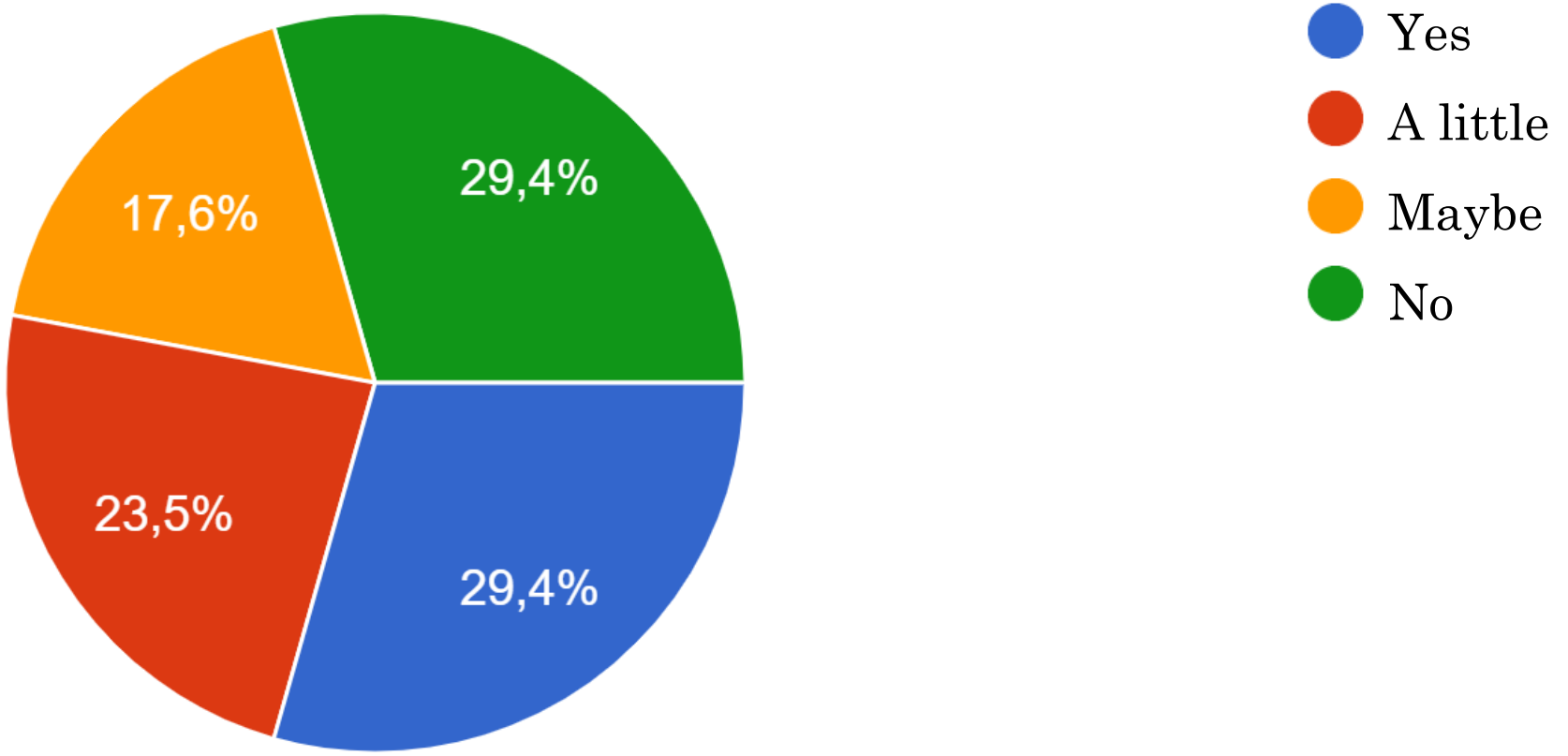
Annex 2: Result of the online form

- Were you happy about the explanations given before the procedure involving the speculum?



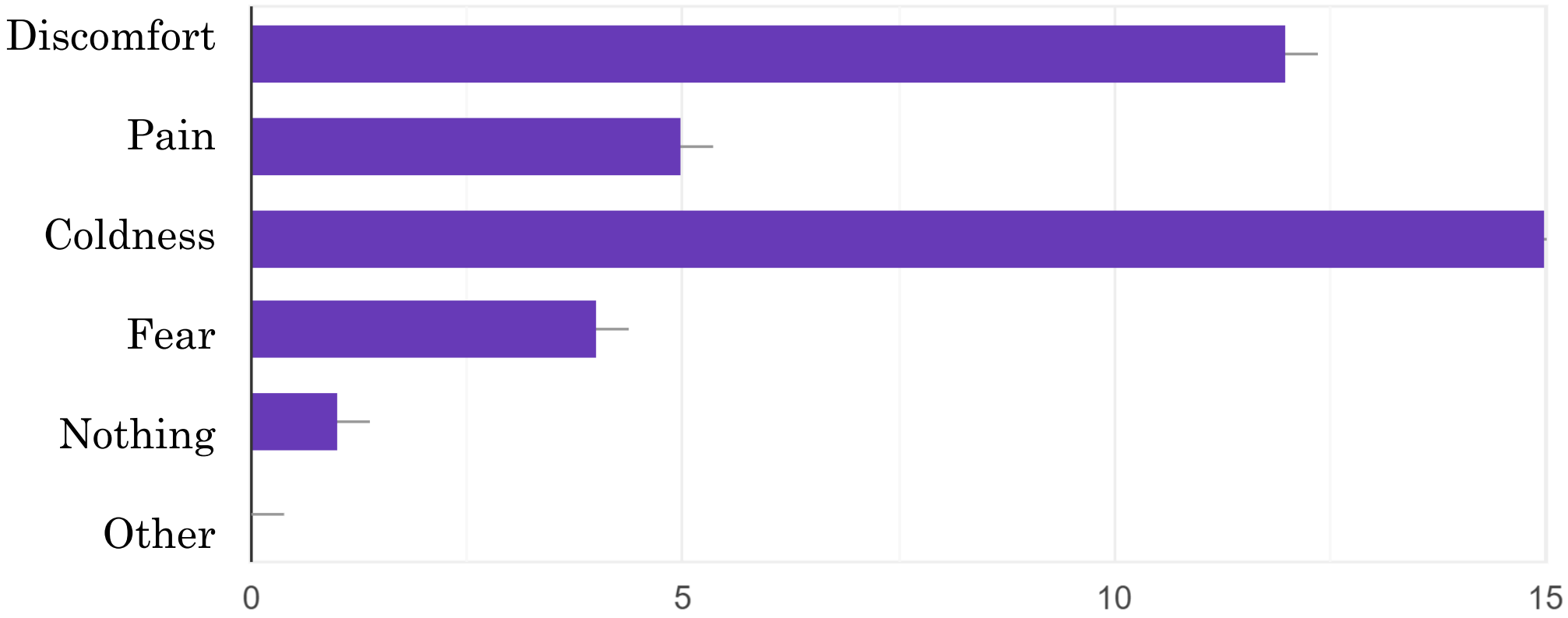
Annex 2: Result of the online form

- Were you happy about the explanations given during the procedure involving the speculum?



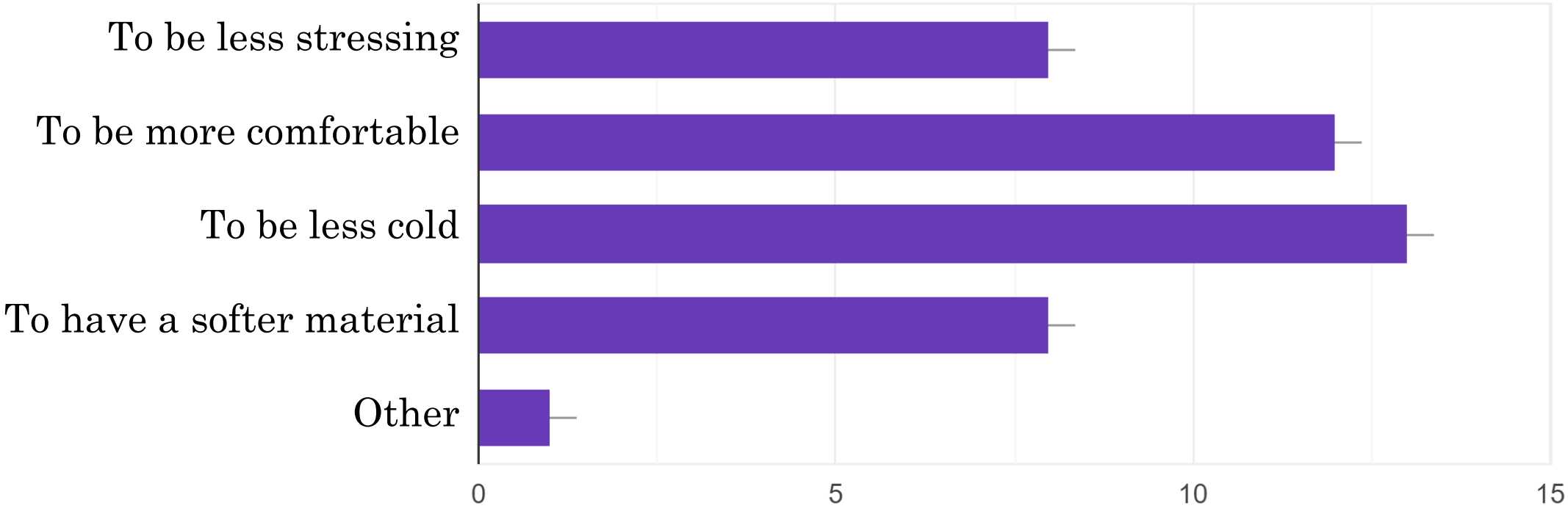
Annex 2: Result of the online form

- Did you experience any of these followings during the procedure?



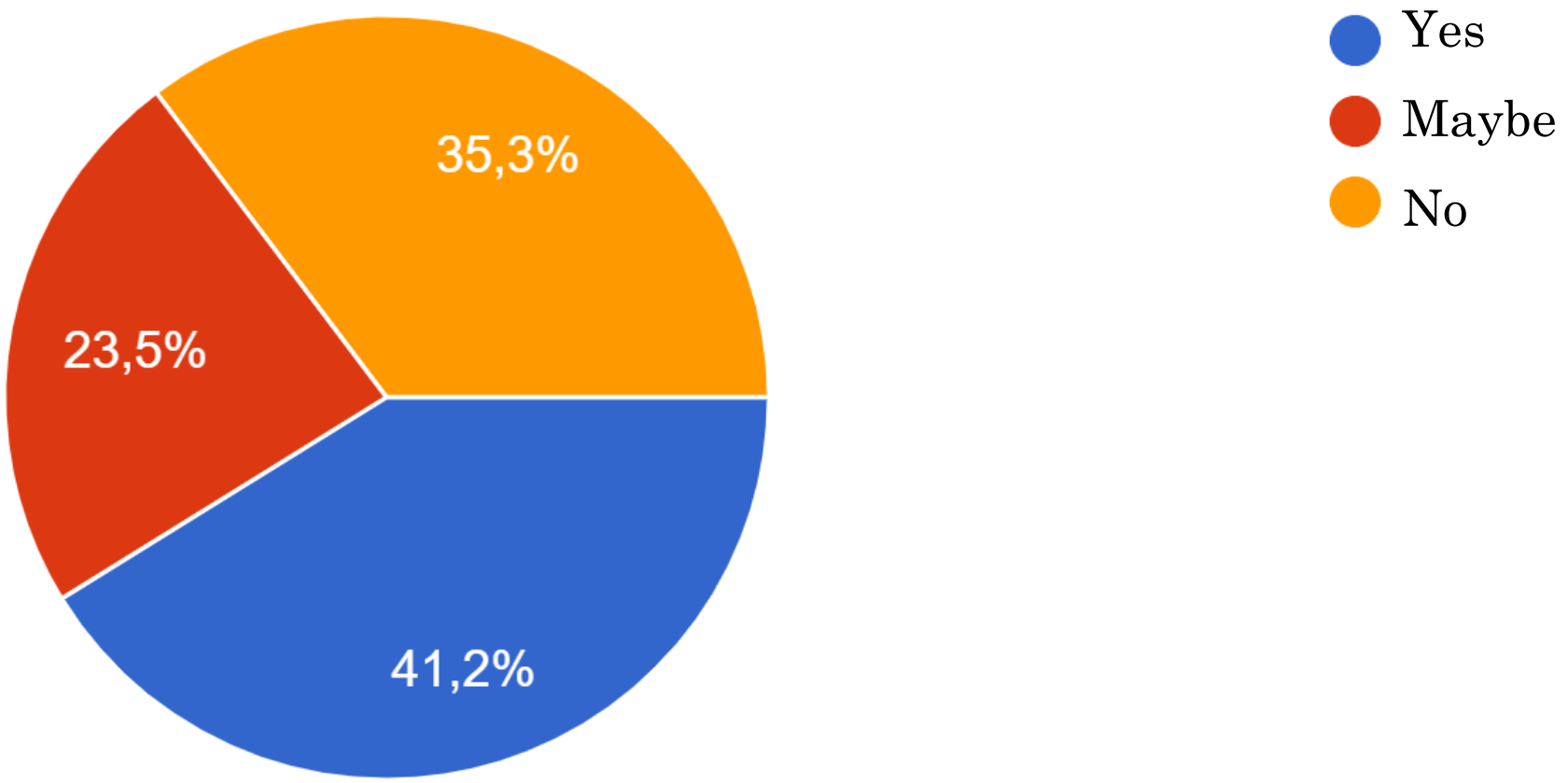
Annex 2: Result of the online form

- What improvements would you like to see made to the speculum?



Annex 2: Result of the online form

- If it was possible, would you like to conduct minor procedures like smear test at home by yourself?



References

References

- Anon (1972) self help clinics. 3 (3), 7–7.
- Bates, C. K. et al. (2011) The Challenging Pelvic Examination. *Journal of general internal medicine : JGIM*. [Online] 26 (6), 651–657.
- Breen, C. (2017). *Women behind speculum redesign say we need gynecological tools designed by people with vaginas*. [online] https://www.thelily.com. Available at: https://www.thelily.com/women-behind-speculum-redesign-say-we-need-gynecological-tools-designed-by-people-with-vaginas/?.
- Calla Health Technologies. (2019). *Callascope*. [online] Available at: https://callahealthfoundation.com/callascope/ [Accessed 9 Mar. 2021].
- Coroflot. (2019). *Lotus: Speculum ReDesign*. [online] Available at: https://www.coroflot.com/dcmailach/Lotus-Speculum-ReDesign [Accessed 9 Mar. 2021].
- daynamailach.com. (2019). *Dayna Mailach - LOTUS: Speculum Redesign*. [online] Available at: https://daynamailach.com/lotus-speculum-redesign [Accessed 9 Mar. 2021].
- Dais, J. (2019). *The Vaginal Speculum Gets a Long-Awaited Redesign | Freethink*. [online] Available at: https://www.freethink.com/videos/vaginal-speculum-pelvic-exam-tool.

References

- Daly, M. (1984) *Gyn/Ecology :* the metaethics of radical feminism. London: Women's Press.
- EngineerDog.com. (2015). *Mechanical Testing 3D Printed Parts: Results and Recommendations*. [online] Available at: https://engineerdog.com/2015/09/02/mechanical-testing-3d-printed-parts-results-and-recommendations/ [Accessed 22 Jun. 2021].
- www.bridea.com.hk. (2013). *Orchid Spec - The New Speculum - Het Nieuwe Speculum*. [online] Available at: http://www.bridea.com.hk [Accessed 9 Mar. 2021].
- iF WORLD DESIGN GUIDE. (2021). *INTIMA*. [online] Available at: https://ifworlddesignguide.com/entry/181865-intima [Accessed 9 Mar. 2021].
- Freyens, A. et al. (2017) Young women describe the ideal first pelvic examination: Qualitative research using semistructured interviews. *Canadian family physician*. 63 (8), e376–e380.
- MOSKOWITZ, R. (2020). *Nella NuSpec by Ceek Women's Health Named Honoree in Fast Company's 2020 Innovation by Design Awards*. [online] Available at: https://www.prweb.com/releases/nella_nuspec_by_ceek_women_s_health_named_honoree_in_fast_companys_2020_innovation_by_design_awards/prweb17448207.htm [Accessed 9 Mar. 2021].
- Quinn, M. J. (1999) An illuminated vaginal speculum. *American journal of obstetrics and gynecology*. [Online] 180 (1), 33–34.

References

- KENT, C. (2020). *Does the vaginal speculum need a redesign? - Medical Technology | Issue 31 | September 2020*. [online] Available at: https://medical-technology.nridigital.com/medical_technology_sep20/vaginal_speculum_redesign [Accessed 9 Mar. 2021].
- RENNER, C. (2006) À propos du spéculum d'étain de Récamier. *Histoire des sciences médicales*. 40 (4), 345–350.
- Matschukat, J. (2019). *Ceek wins "Commercial Equipment" Core77 Design Awards 2019*. [online] Available at: https://ceekwomenshealth.com/ceek-news/2019/12/31/ceek-wins-commercial-equipment-core77-design-awards-2019 [Accessed 9 Mar. 2021].
- Miller, J. . et al. (2007) Test-retest reliability of an instrumented speculum for measuring vaginal closure force. *Neurourology and urodynamics*. [Online] 26 (6), 858–863.

References

- yonacare.com. (2017). *Speculum — Yona Care*. [online] Available at: https://yonacare.com/Speculum.
- Ott, K., Collard, J. and East, B. (1997). *Speculum Gonflable*. [online] Available at: https://patentscope.wipo.int/search/fr/detail.jsf?docId=WO1997024975&tab=DRAWINGS [Accessed 9 Mar. 2021].
- Million, E. et al. (2020) The first pelvic examination: A rite of passage for the women. A qualitative study about French women. *The European journal of general practice*. [Online] 26 (1), 61–69.

References

- Williams, A. A. & Williams, M. (2013) *A Guide to Performing Pelvic Speculum Exams: A Patient-Centered Approach to Reducing Iatrogenic Effects. Teaching and learning in medicine.* [Online] 25 (4), 383–391.
- Asiedu, M. N. et al. (2017) *Design and preliminary analysis of a vaginal inserter for speculum-free cervical cancer screening. PloS one.* [Online] 12 (5), e0177782–e0177782.
- Taylor, G. A. et al. (2017) *Improving the Pelvic Exam Experience: A Human-Centered Design Study. The Design journal.* [Online] 20 (sup1), S2348–S2362.
- Rossmann, J. S. (2008). *Built to spec?: The vaginal speculum as a case study of inadequate design. Ambidextrous, 47–49.* Retrieved from http://dspace.lafayette.edu/xmlui/handle/10385/589
- Jones, C. L. et al. (2013) Usability study of a novel, self-lighted, disposable speculum: military applications. Military medicine. [Online] 178 (4), e489–e492.

References

- Cooper C. (2021). *Personalized Medical Devices - A New Trend*. [online] Available at: https://www.team-consulting.com/insights/customising-medical-devices-personalisation-or-standardisation/ [Accessed 15 Apr. 2021].
- Hanon, M. M. et al. (2020) Effect of print orientation and bronze existence on tribological and mechanical properties of 3D-printed bronze/PLA composite. *International journal of advanced manufacturing technology*. [Online] 108 (1-2), 553–570.
- Kurtz, S. M. & Devine, J. N. (2007) PEEK biomaterials in trauma, orthopedic, and spinal implants. Biomaterials. [Online] 28 (32), 4845–4869. Selim Kadioglu et al. (2017) A Classical Wooden Vaginal Speculum Mentioned in Old Medical Manuscripts. *Archives of Iranian medicine*. 20 (3), 193–.
- Taylor, G. A. et al. (2017) Improving the Pelvic Exam Experience: A Human-Centered Design Study. *The Design journal*. [Online] 20 (sup1), S2348–S2362.